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Guidelines for Determining the Probability of Causation and Methods for Radiation Dose Reconstruction Under the Employees Occupational Illness Compensation Program Act of 2000; Final Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 81

RIN 0920–ZA01

Guidelines for Determining the Probability of Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Final Rule

AGENCY: Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: This rule implements select provisions of the Energy Employees Occupational Illness Compensation Program Act of 2000 (''EEOICPA'' or ''Act''). The Act requires the promulgation of guidelines, in the form of regulations, for determining whether an individual with cancer shall be found, ''at least as likely as not,'' to have sustained that cancer from exposure to ionizing radiation in the performance of duty for nuclear weapons production programs of the Department of Energy and its predecessor agencies. The guidelines will be applied by the U.S. Department of Labor, which is responsible for determining whether to award compensation to individuals seeking federal compensation under the Act.

DATES: *Effective Date:* This final rule is effective May 2, 2002.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS-R45, Cincinnati, OH 45226, Telephone 513–841–4498 (this is not a toll-free number). Information requests can also be submitted by e-mail to *OCAS@CDC.GOV*

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Authority

The Energy Employees Occupational Illness Compensation Program Act of 2000(''EEOICPA''), 42 U.S.C. 7384–7385 [1994, supp. 2001], established a compensation program to provide a lump sum payment of $150,000 and medical benefits as compensation to covered employees suffering from designated illnesses (i.e. cancer resulting from radiation exposure, chronic beryllium disease, or silicosis) incurred as a result of their exposures while in the performance of duty for the Department of Energy (''DOE'') and certain of its vendors, contractors, and subcontractors. This legislation also provided for payment of compensation to certain survivors of covered employees.

EEOICPA instructed the President to designate one or more federal agencies to carry out the compensation program. Pursuant to this statutory provision, the President issued Executive Order 13179 titled Providing Compensation to America's Nuclear Weapons Workers, which assigned primary responsibility for administering the compensation program to the Department of Labor (''DOL''). 65 FR 77,487 (Dec. 7, 2000). DOL published an interim final rule governing its administration of EEOICPA on May 25, 2001 (20 CFR Parts 1 and 30).

The Executive Order directed the Department of Health and Human Services (''HHS'') to perform several technical and policymaking roles in support of the DOL program:

(1) HHS is to develop guidelines to be used by DOL to assess the likelihood that an employee with cancer developed that cancer as a result of exposure to radiation in performing his or her duties at a DOE facility or Atomic Weapons Employer (''AWE'') facility. These ''Probability of Causation'' guidelines are the subject of this final rule, and were initially proposed for public comment in a notice of proposed rulemaking published on October 5, 2001.

(2) HHS is also to establish methods to estimate radiation doses (''dose reconstruction'') for certain individuals with cancer applying for benefits under the DOL program, and HHS is to implement these methods in a program of dose reconstruction for EEOICPA claims. HHS published these methods as an interim final rule under 42 CFR part 82 on October 5, 2001, and is publishing them as a final rule simultaneously in this issue of the **Federal Register**. HHS is presently applying these methods to conduct the program of dose reconstruction required by EEOICPA.

(3) HHS is to staff the Advisory Board on Radiation and Worker Health and provide it with administrative and other necessary support services. The Board, a federal advisory committee, was appointed by the President in November 2001. It was first convened on January 22, 2001, and is advising HHS in implementing its roles under EEOICPA described here.

(4) Finally, HHS is to develop and apply procedures for considering petitions by classes of employees at DOE or AWE facilities seeking to be added to the Special Exposure Cohort established under EEOICPA. Employees included in the Special Exposure Cohort who have a specified cancer and meet other conditions, as defined by EEOICPA and DOL regulations (20 CFR 30), qualify for compensation under EEOICPA. HHS has developed proposed procedures for considering Special Exposure Cohort petitions which will be published soon in the **Federal Register**. HHS will obtain public comment and a review by the Advisory Board on Radiation and Worker Health before these procedures are made final and implemented.

As provided for under 42 U.S.C. 7384p, HHS is implementing its responsibilities with the assistance of the National Institute for Occupational Safety and Health (''NIOSH''), an institute of the Centers for Disease Control and Prevention, HHS.

B. Purpose of Probability of Causation Guidelines

Under EEOICPA, a covered employee seeking compensation for cancer, other than as a member of the Special Exposure Cohort seeking compensation for a specified cancer, is eligible for compensation only if DOL determines that the cancer was ''at least as likely as not'' (a 50% or greater probability) caused by radiation doses incurred in the performance of duty while working for DOE and/or an atomic weapons employer (AWE) facility. These guidelines provide DOL with the procedure to make these determinations, and specify the information DOL will use.

HHS notes that EEOICPA does not authorize the establishment of new radiation protection standards through the promulgation of these guidelines, and these guidelines do not constitute such new standards.

C. Statutory Requirements for Probability of Causation Guidelines

EEOICPA has several general requirements concerning the development of these guidelines. It requires the guidelines provide for determinations that are based on the radiation dose received by the employee, incorporating the methods of dose reconstruction to be established by HHS. It requires determinations be based on the upper 99 percent confidence interval of the probability of causation in the radioepidemiological tables published under section 7(b) of the Orphan Drug Act (42 U.S.C. 241 note), as such tables may be updated. EEOICPA also requires HHS to consider the type of cancer, past health-related activities, the risk of developing a radiation-related cancer from workplace exposure, and other relevant factors. 42 U.S.C. 7384n(c). It is also important to

note EEOICPA does *not* include a requirement limiting the types of cancers to be considered radiogenic for these guidelines.

D. Understanding Probability of Causation

Probability of Causation is a technical term generally meaning an estimate of the percentage of cases of illness caused by a health hazard among a group of persons exposed to the hazard. This estimate is used in compensation programs as an estimate of the probability or likelihood that the illness of an individual member of that group was caused by exposure to the health hazard. Other terms for this concept include ''assigned share'' and ''attributable risk percent'.

In this rule, the potential hazard is ionizing radiation to which U.S. nuclear weapons workers were exposed in the performance of duty; the illnesses are specific types of cancer. The probability of causation (PC) is calculated as the risk of cancer attributable to radiation exposure (RadRisk) divided by the sum of the baseline risk of cancer to the general population (BasRisk) plus the risk attributable to the radiation exposure, then multiplied by 100 percent, as follows:

$$\frac{\text{RadRisk}}{\text{RadRisk} + \text{BasRisk}} \times 100\% = \text{PC}$$

This calculation provides a percentage estimate between 0 and 100 percent, where 0 would mean 0 likelihood that radiation caused the cancer and 100 would mean 100 percent certainty that radiation caused the cancer.

Scientists evaluate the likelihood that radiation caused cancer in a worker by using medical and scientific knowledge about the relationship between specific types and levels of radiation dose and the frequency of cancers in exposed populations. Simply explained, if research determines that a specific type of cancer occurs more frequently among a population exposed to a higher level of radiation than a comparable population (a population with less radiation exposure but similar in age, gender, and other factors that have a role in health), and if the radiation exposure levels are known in the two populations, then it is possible to estimate the proportion of cancers in the exposed population that may have been caused by a given level of radiation.

If scientists consider this research sufficient and of reasonable quality, they can then translate the findings into a series of mathematical equations that estimate how much the risk of cancer in a population would increase as the dose of radiation incurred by that population increases. The series of equations, known as a dose-response or quantitative risk assessment model, may also take into account other health factors potentially related to cancer risk, such as gender, smoking history, age at exposure (to radiation), and time since exposure. The risk models can then be applied as an imperfect but reasonable approach to determine the likelihood that the cancer of an individual worker was caused by his or her radiation dose.

E. Development and Use of the RadioEpidemiological Tables and Interactive RadioEpidemiological Program

In 1985, in response to a congressional mandate in the Orphan Drug Act, a panel established by the National Institutes of Health developed a set of Radioepidemiological Tables. The tables serve as a reference tool providing probability of causation estimates for individuals with cancer who were exposed to ionizing radiation. Use of the tables requires information about the person's dose, gender, age at exposure, date of cancer diagnosis and other relevant factors. The tables are used by the Department of Veterans Affairs (DVA) to make compensation decisions for veterans with cancer who were exposed in the performance of duty to radiation from atomic weapon detonations.

The primary source of data for the 1985 tables is research on cancer-related deaths occurring among Japanese atomic bomb survivors from World War II.

The 1985 tables are presently being updated by the National Cancer Institute (NCI) and the Centers for Disease Control and Prevention [1] to incorporate progress in research on the relationship between radiation and cancer risk. The draft update has been reviewed by the National Research Council [2] and by NIOSH. DOL will employ the updated version of the tables, with modifications important to claims under EEOICPA (described below under ''G'' and in response to public comments under ''II''), as a basis for determining probability of causation for employees covered under EEOICPA.

A major scientific change achieved by this update is the use of risk models developed from data on the occurrence of cancers (cases of illness) rather than the occurrence of cancer deaths among Japanese atomic bomb survivors. The risk models are further improved by being based on more current data as well. Many more cancers have been modeled in the revised report. The new risk models also take into account factors that modify the effect of radiation on cancer, related to the type of radiation dose, the amount of dose, and the timing of the dose.

A major technological change accompanying this update, which represents a scientific improvement, is the production of a computer software program for calculating probability of causation. This software program, named the Interactive RadioEpidemiological Program (IREP), allows the user to apply the NCI risk models directly to data on an individual employee. This makes it possible to estimate probability of causation using better quantitative methods than could be incorporated into printed tables. In particular, IREP allows the user to take into account uncertainty concerning the information being used to estimate probability of causation. There typically is uncertainty about the radiation dose levels to which a person has been exposed, as well as uncertainty relating levels of dose received to levels of cancer risk observed in study populations.

Accounting for uncertainty is important because it can have a large effect on the probability of causation estimates. DVA, in their use of the 1985 Radioepidemiological Tables, uses the probability of causation estimates found in the tables at the upper 99 percent credibility limit. This means when DVA determines whether the cancer of a veteran was more likely than not caused by radiation, they use the estimate that is 99 percent certain to be greater than the probability that would be calculated if the information on dose and the risk model were perfectly accurate. Similarly, these HHS guidelines, as required by EEOICPA, will use the upper 99 percent credibility limit to determine whether the cancers of employees are at least as likely as not caused by their occupational radiation doses. 42 U.S.C. 7384n(c)(3)(A). This will help minimize the possibility of denying compensation to claimants under EEOICPA for those employees with cancers likely to have been caused by occupational radiation exposures.

F. Use of IREP for Energy Employees

The risk models developed by NCI and CDC for IREP provide the primary basis for developing guidelines for estimating probability of causation under EEOICPA. They directly address 33 cancers and most types of radiation

[1] Draft Report of the NCI–CDC Working Group to Revise the 1985 NIH Radioepidemiological Tables, May 31, 2000.

[2] A Review of the Draft Report of the NCI–CDC Working Group to Revise the ''1985 Radioepidemiological Tables'', National Research Council.

exposure relevant to employees covered by EEOICPA. These models take into account the employee's cancer type, year of birth, year of cancer diagnosis, and exposure information such as years of exposure, as well as the dose received from gamma radiation, x rays, alpha radiation, beta radiation, and neutrons during each year. Also, the risk model for lung cancer takes into account smoking history and the risk model for skin cancer takes into account race/ethnicity. None of the risk models explicitly accounts for exposure to other occupational, environmental, or dietary carcinogens. Models accounting for these factors have not been developed and may not be possible to develop based on existing research. Moreover, DOL could not consistently or efficiently obtain the data required to make use of such models.

IREP models do not specifically include cancers as defined in their early stages: carcinoma in situ (CIS). These lesions are becoming more frequently diagnosed, as the use of cancer screening tools, such as mammography, have increased in the general population. The risk factors and treatment for CIS are frequently similar to those for malignant neoplasms, and, while controversial, there is growing evidence that CIS represents the earliest detectable phase of malignancy.[3] Therefore, for determining compensation under EEOICPA, HHS requires that CIS be treated as a malignant neoplasm of the specified site.

Cancers identified by their secondary sites (sites to which a malignant cancer has spread), when the primary site is unknown, raise another issue for the application of IREP. This situation will most commonly arise when death certificate information is the primary source of a cancer diagnosis. It is accepted in medicine that cancer-causing agents such as ionizing radiation produce primary cancers. This means, in a case in which the primary site of cancer is unknown, the primary site must be established by inference to estimate probability of causation.

HHS establishes such assignments in these guidelines, based on an evaluation of the relationship between primary and secondary cancer sites using the National Center for Health Statistics (NCHS) Mortality Database for years 1995–1997. Because national cancer incidence databases (*e.g.*, the National Cancer Institute's Surveillance, Epidemiology and End Results program) do not contain information about sites of metastasis, the NCHS database is the best available data source at this time to assign the primary site(s) most likely to have caused the spread of cancer to a known secondary site. For each secondary cancer, HHS identified the set of primary cancers producing approximately 75% of that secondary cancer among the U.S. population (males and females were considered separately). The sets are tabulated in this rule (Table 1). DOL will determine the final assignment of a primary cancer site for an individual claim on a case-by-case basis, as the site among possible primary sites which results in the highest probability of causation estimate.

Employees diagnosed with two or more primary cancers also raise a special issue for determining probability of causation. Even under the assumption that the biological mechanisms by which each cancer is caused are unrelated, uncertainty estimates about the level of radiation delivered to each cancer site will be related. While fully understanding this situation requires statistical training, the consequence has simple but important implications. Under this rule, instead of determining the probability that each cancer was caused by radiation independently, DOL will perform an additional statistical procedure following the use of IREP to determine the probability that at least one of the cancers was caused by the radiation. This approach is important to the claimant because it would determine a higher probability of causation than would be determined for either cancer individually.

G. Limitations of IREP for Energy Employees

NCI is developing IREP to serve the needs of DVA in deciding cancer compensation claims for veterans. This means IREP has to be adapted in various ways to meet the needs of DOL, because the radiation exposure experience of employees covered by EEOICPA differs substantially.

Some employees covered by EEOICPA were exposed to radon and other sources of high linear energy transfer (LET) radiation. This type of radiation exposure has unique properties affecting cancer risk, which are not addressed in the risk models included in IREP. Specifically, the IREP risk models do not account for a possible inverse dose-rate effect for high-LET radiation exposures. This effect means at any particular dose level, especially higher dose levels, a dose of high LET radiation incurred gradually over time is more likely to cause cancer than the same total dose incurred quickly or at once. A substantial body of research supports this finding, including studies of uranium miners, [4] patients exposed to bone-seeking radium alpha particles,[5] and research on the cancer effects of high LET radiation in animals.[6] Because high-LET radiation is an important type of radiation exposure among employees covered by EEOICPA, NIOSH has modified IREP to include uncertainty associated with the assumption of an inverse dose-rate effect for these exposures.

The DOE workforce has been exposed to various types of neutron energies and these exposures are frequently documented in the worker's dosimetry records. The relative biological effectiveness (RBE) of radiation exposure, a factor in cancer risk models that accounts for the differing level of cancer risk associated with different forms of radiation, varies as a function of neutron energy.[7] This variation in RBE related to differing neutron energy is not accounted for in the current version of IREP, which contains a single neutron RBE distribution. Therefore, NIOSH has modified IREP for DOE workers to include different RBE distributions for neutrons of various energies.

The currently public draft of IREP does not incorporate a unique lung cancer model for radon exposure, which is an important exposure for some workers covered under EEOICPA. Using epidemiologic evidence on the lung carcinogenicity of radon exposures, NCI

[3] Kerlikowske, K, J Barclay, D Grady, EA Sickles, and V Ernster. ''Comparison of risk factors for ductal carcinoma in situ and invasive breast cancer.'' *J. Natl. Canc. Inst.* 89:76–82, 1997.

Grippo, PJ, and EP Sandgren. ''Highly invasive transitional cell carcinoma of the bladder in a simian virus 40 T-antigen transgenic mouse model.'' Am. J. Pathol. 157:805–813, 2000.

Correa P, ''Morphology and natural history of cancer precursors'' Chapter 4 in: Cancer Epidemiology and Prevention, 2nd Edition, D Schottenfeld and JF Fraumeni, Jr, eds. New York: Oxford University Press, 1996.

[4] Hornung RW, Meinhardt TJ. Quantitative risk assessment of lung cancer in U.S. uranium miners. Health Phys 52: 417–430, 1987.

Lubin JH, Boice JD Jr, Edling C, et al. Radon-exposed underground miners and the inverse dose-rate (protraction enhancement) effects. Health Phys 69:494–550, 1995.

[5] Mays CW, Spiess H. Bone sarcomas in patients given radium-224. In: Radiation Carcinogenesis: Epidemiology and Biological Significance. Boice JD Jr, Fraumeni JF Jr (eds): New York: Raven Press, pp 241–252, 1984.

[6] Luebeck EG, Curtis SB, Cross FT, Moolgavkar SH. Two-stage model of radon-induced malignant lung tumors in rats: effects of cell killing. Radiat. Res. 145:163–173, 1996.

Hall EJ, Miller RC, Brenner DJ. Neoplastic transformation and the inverse dose-rate effect for neutrons. Radiat. Res. 128 (Suppl): S75–S80, 1991.

[7] International Commission on Radiological Protection (ICRP) 60: ''1990 Recommendations of the International Commission on Radiological Protection.'' Ann. ICRP 21 (1–3): 1–201.

has incorporated a lung cancer model for radon exposures into IREP. The data source for this model is the analysis conducted by the federal Radiation Exposure Compensation Act Committee.[8]

NIOSH has changed IREP to modify an assumption for non-leukemia cancers that low-level acute radiation doses (defined in IREP as doses between 3 and 30 cSv) cause less risk, per unit of dose, than higher level acute doses. NIOSH will use an uncertainty distribution for the dose and dose rate effectiveness factor (DDREF) that more heavily weights a DDREF of one, reducing the distinction in risk effects for low-level acute doses. A recent study of the Japanese atomic bomb survivors supports this change.[9]

Additionally, some employees covered by EEOICPA were required, as a condition of employment, to undergo routine medical screening with x rays. The dose resulting from these x rays will be included in their dose reconstruction. This required NIOSH to add to IREP an RBE distribution appropriate to the low-energy form of radiation produced from some of these x rays. [10]

Research has found bone cancer risk substantially and significantly elevated among animals and humans exposed to certain forms of high-LET radiation. [11] Although Japanese A-bomb survivor risk models for bone cancer have been used for a plutonium risk assessment, [12] they are based on highly unstable risk models. Therefore, NIOSH is using in IREP the risk model recommended in the NCI-IREP documentation, which is based on all residual cancers, including bone.

Limitations of current research and development have prevented NIOSH from considering and implementing all possible improvements to IREP at this time. In the future, NIOSH may make additional changes in IREP to address differences in radiation-related cancer risk between Japanese atomic bomb survivors and employees involved in nuclear weapons production. Some research has shown substantial differences in risk for certain cancers, such as brain cancer and multiple myeloma [13]. The radiation-related risk of these cancers is significantly elevated among employees involved in nuclear weapons production, whereas it is not among the Japanese study population. The IREP risk models for these cancers were produced using data from the Japanese study population.

Similarly, it may be possible to improve the fit of IREP risk models to employees covered by EEOICPA with respect to differences between the frequency of certain cancers in the general population in the United States versus Japan. The IREP risk models include a simplistically derived factor (risk transfer) that accounts for these differences, based on expert judgment. For some cancers, such as breast and stomach cancer, sufficient research may exist to improve this factor. In addition, where current IREP risk models could be replaced with risk models based on studies of U.S. DOE workers, or other U.S. populations, this factor could be omitted entirely. The potential future use of risk models based on studies of U.S. DOE workers may also eliminate limitations arising because data are sparse for certain cancers among the Japanese atomic bomb survivors, such as most specific types of leukemia. Using data on the Japanese cohort, the effect on risk of age at time of exposure to radiation, an important modifier of leukemia risk, cannot be estimated for specific types of leukemia, except chronic myeloid leukemia. It can only be estimated for other leukemia types by using a general leukemia model that combines data from cases of different types of leukemia.

Finally, NIOSH may make modifications in cancer risk models in IREP, as appropriate and if feasible, to account for the changing frequency among the general population (baseline rates) of certain types of cancer in the United States. Certain types of cancer (*e.g.*, lung cancer among women, breast cancer) have become more frequent in recent decades. Similarly, NIOSH may make modifications in cancer risk models to reflect the differing frequency of certain types of cancer among different racial and ethnic groups in the United States (*e.g.*, multiple myeloma). The effect of these modifications, at such time as they may become available, would be to improve the accuracy of probability of causation estimates.

H. Procedures for Review and Public Comment on NIOSH–IREP

As described under Section G above, some current and potential future changes to the cancer risk models in IREP are particularly appropriate for addressing the radiation exposures and statutory requirements of claimants under EEOICPA. As a result, the version of IREP to include NIOSH modifications will be unique and distinguished as ''NIOSH–IREP.'' This version, which DOL will use to estimate probability of causation under EEOICPA, will be reviewed by the Advisory Board on Radiation and Worker Health. NIOSH–IREP is available for public review on the NIOSH homepage at: *www.cdc.gov/niosh/ocas/ocasirep/html.* It includes documentation of underlying risk models and calculations. The public can obtain complete information about NIOSH–IREP by contacting NIOSH at its toll-free telephone information service: 1–800–35–NIOSH (1–800–356–4674).

The public may comment on NIOSH–IREP at any time. Comments can be submitted by e-mail to *OCAS@CDC.GOV,* or by mailing written comments to: NIOSH–IREP Comments, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS–R45, Cincinnati, Ohio 45226. All comments will be considered. In addition, NIOSH will forward all substantive comments to the Advisory Board on Radiation and Worker Health, which will have an ongoing role to review and advise NIOSH on possible changes to NIOSH–IREP, as described in this rule.

I. Operating Guide for NIOSH–IREP

DOL will use procedures specified in the NIOSH–IREP Operating Guide to calculate probability of causation estimates under EEOICPA. The guide provides current, step-by-step instructions for the operation of NIOSH–IREP. The procedures include entering personal, diagnostic, and exposure data; setting/confirming appropriate values for variables used in calculations; conducting the calculation; and, obtaining, evaluating, and reporting results.

[8] Final Report of the Radiation Exposure Compensation Act Committee, submitted to the Human Radiation Interagency Working Group, July 1996 (Appendix A), 30 pp (plus Figures).

[9] Pierce DA and Preston DL ''Radiation-related cancer risks at low doses among atomic bomb survivors.'' Radiat. Res. 154:178–186, 2000.

[10] ICRU Report 40: The quality factor in radiation protection. Internat. Commission on Radiat. Units and Meas., 33 pp, 1986.

Hall EJ. ''Linear energy transfer and relative biological effectiveness'' Chapter 9 in Radiobiology for the Radiobiologist, 4th Edition. Philadelphia: J.B. Lippincott, 1994.

[11] International Agency for Research on Cancer (IARC). IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol. 78 Ionizing Radiation, Part 2: Some Internally Deposited Radionuclides. Lyon, France: IARC Press, 595 pp, 2001.

[12] Grogan HA, Sinclair WK, and Voillequé PG. ''Risks of fatal cancer from inhalation of 239,240plutonium by humans: a combined four-method approach with uncertainty evaluation'' Health Physics 80:447–461, 2001.

[13] Alexander V and DiMarco JH. ''Reappraisal of brain tumor risk among U.S. nuclear workers: a 10–year review.'' Occupational Medicine: State of the Art Reviews 16(2):289–315, 2001.

Cardis E, Gilbert ES, Carpenter L, et al. ''Effects of low doses and low dose rates of external ionizing radiation: cancer mortality among nuclear industry workers in three countries.'' Radiat. Res. 142:117–132, 1995.

An initial version of the NIOSH–IREP Operating Guide is available to the public online on the NIOSH homepage at: *www.cdc.gov/niosh/ocas/ocasirep/html*. The public can obtain printed copies by contacting NIOSH at its toll-free telephone information service: 1–800–35–NIOSH (1–800–356–4674).

II. Summary of Public Comments

On October 5, 2001, HHS proposed guidelines for determining probability of causation under EEOICPA (42 CFR 81; see 66 FR 50967). HHS initially solicited public comments from October 5 to December 4, 2001. The public comment period was reopened subsequently from January 17, 2002 to January 23, 2002 for public comments, and from January 17, 2002 to February 6, 2002, for comments from the Advisory Board on Radiation and Worker Health (67 FR 2397).

HHS received comments from 12 organizations and 24 individuals. Organizations commenting included several labor unions representing DOE workers, a community based organization, an administrative office of the University of California, several DOE contractors, and several federal agencies. A summary of these comments and HHS responses is provided below. These are organized by general topical area.

A. Appropriateness of Adapting Compensation Policy Used for Atomic Veterans

One commenter requested explanation of the appropriateness of adapting existing compensation policy for atomic veterans to a compensation program for nuclear weapons workers. The comment appears to question whether this existing policy for atomic veterans is an appropriate starting point from which to develop compensation policy under EEOICPA. In the notice of proposed rulemaking, HHS had solicited public comment on whether it had appropriately adapted compensation policy for atomic veterans to meet the needs of this workforce, which has a substantially different occupational and radiation exposure experience.

Congress determined the veteran's compensation policy as a starting point for HHS. It did so by requiring the determination of probability of causation based on radiation doses and the use of the NIH Radioepidemiological Tables, and by requiring that the cancer covered in a claim be determined to be ''at least as likely as not'' caused by radiation doses incurred in the performance of duty, based on the upper 99 percent credibility limit. These are defining features of compensation policy for atomic veterans.

The public should also recognize that the Radioepidemiological Tables required years to initially develop and then additional years to update (the update is not completed). Without this critical, highly sophisticated element developed for the veterans' program, it would not have been possible to establish and implement a policy for nuclear weapons workers in a timely fashion.

HHS adapted these policies for nuclear weapons workers through two prominent measures, discussed in the notice of proposed rulemaking and below. HHS included provisions to allow NIOSH to adapt the cancer risk models in the latest version of the NIH Radioepidemiological Tables to reflect the unique radiation exposure experience of nuclear weapons workers. And HHS established transparent, objective procedures for DOL to handle a variety of circumstances in which various information relevant to determining probability of causation will be unknown. The majority of comments received on this rule suggest most commenters view as appropriate the measures HHS has taken to adapt existing compensation policy to this new program.

B. Compensability

Various comments relating to the use of these guidelines were received. Specifically, HHS received comments on: awarding compensation based upon a proportional level of probability of causation; the use of the upper 99 percent confidence limit to estimate probability of causation; awarding compensation for employees who incurred radiation doses within regulated radiation safety limits; automatically qualifying employees who incurred doses in excess of the maximum allowable radiation dose under Atomic Energy Commission regulations; waiving dose reconstruction and probability of causation for employees with rare cancers; and automatically compensating employees for whom DOE is unwilling or unable to provide employment records.

The development and use of these guidelines for determining compensability and the benefit structure are statutorily mandated and therefore these comments were not adopted.

One commenter suggested prohibiting the use of probability of causation findings as proof of fault in litigation. This suggestion was not adopted because prohibiting the use of probability of causation findings for litigation purposes is not authorized by the statute. However, because these findings will be based on NIOSH dose reconstructions, which will not always produce complete or best estimates of the actual doses received by an individual, [14] HHS does not believe these findings should be used for any purpose other than the adjudication of claims under EEOICPA.

C. Need for Peer Review

Several commenters recommended that HHS obtain peer review of the cancer risk models that comprise NIOSH–IREP, and of changes to NIOSH–IREP, as it is updated based on progress in the underlying sciences. Several commenters recognized that the Advisory Board on Radiation and Worker Health is intended by HHS as one means of obtaining such peer review, but the commenters raised concerns about whether the Board would have sufficient expertise for this purpose.

HHS recognizes the importance of peer review. Consequently, as indicated above, the National Cancer Institute obtained peer review of IREP by the National Research Council. NCI and NIOSH have made modifications in IREP consistent with this peer review. NIOSH has also obtained peer-review by independent subject matter experts of changes developed by NIOSH to adapt IREP to the experience of nuclear weapons workers. These peer-reviews are posted on the NIOSH website and are also available to the public by request.

In addition, the Advisory Board on Radiation and Worker Health will be reviewing the cancer risk models in NIOSH–IREP, as indicated above and in the notice of proposed rulemaking. Contrary to the public comments noted above, HHS finds the Board has appropriate expertise for such a review, including eminent physicians and scientists from the field of health physics. Moreover, the Board maintains the option to commission additional independent scientists to participate in the Board's review. HHS also has the option to obtain additional peer reviews by the National Academy of Sciences, as recommended by some commenters.

In response to comments recommending peer review and to the recommendations of the Advisory Board on Radiation and Worker Health discussed below, HHS has added a new requirement to this rule to affirm the commitment of HHS to involve the

[14] For explanation of these possible limitations of NIOSH dose reconstructions, see the discussion under ''II. Summary of Public Comments; A. Purpose of the Rule'' in the preamble of 42 CFR Part 82 (the HHS dose reconstruction rule).

Board in peer-review of future decisions to change NIOSH–IREP and to ensure this process is open to public participation. These provisions, which were previously contained in the preamble of the notice of proposed rulemaking, are now incorporated into the rule itself under § 81.12.

One commenter recommended HHS extend the comment period of the rule to provide the public with additional time to review NIOSH–IREP.

As indicated in the notice of proposed rulemaking and above, the public can comment on NIOSH–IREP at any time. The rule comment period applies only to provisions of the rule itself.

D. Updating NIOSH–IREP to Remain Current With Science

Commenters supported the intent of HHS to update NIOSH–IREP as scientific progress enables HHS to improve the cancer risk models. Two commenters recommended that DOL apply updates to NIOSH–IREP retrospectively to claims that were denied on the basis of a probability of causation finding that might change as a result of the update.

Under 42 CFR 81.12 NIOSH will notify the public and DOL when changes to NIOSH–IREP are completed and explain the effect of changes on probability of causation estimates. This will enable DOL and claimants with denied claims to identify denied claims potentially affected by the changes and evaluate the effect of this new information.

E. Chemical or Non-Occupational Radiation Exposures as Risk Factors

Some nuclear weapons workers were exposed to potential and known chemical carcinogens as well as radiation in the performance of duty. Several commenters urged that cancer risk models in NIOSH–IREP take into account the effects that these combined or ''mixed'' exposures might have on risk associated with radiation exposure.

There is no adjustment in NIOSH–IREP for chemical exposures. It is not clear that the state of science presently could support risk adjustments that account for possibly differing roles of chemical exposures. A second, probably overriding, practical concern is whether this compensation program for nuclear weapons workers, which already requires the collection and consideration of large amounts of information, could produce fair, timely decisions with the addition of a substantial new informational burden. New information would be required for each claim regarding the type, level, duration, and timing of relevant chemical exposures, as well as the use of administrative measures and protective equipment to protect exposed workers.

Despite these limitations, NIOSH will consider taking into account the effect of mixed exposures at such time as this may become scientifically supportable and feasible. HHS has added section 81.10(b)(4) to specifically include this possibility.

Several other commenters made similar but distinct recommendations to modify the cancer risk models in NIOSH–IREP to account for cancer risks that might be independent of radiation risks, arising from occupational and community exposures to chemicals or non-occupational exposures to radiation. Some commonplace examples of such exposures might include exposures to solvents or preservatives used at work or home, radon in the home, second-hand tobacco smoke, or sun exposure. The recommendation relates to the fact that groups have different ''background'' risks of cancers depending on their exposure to these various carcinogens. Groups with higher than normal background risks might be shown in studies of radiation risks to have lower increases in cancer risk attributable to radiation. Likewise, groups with lower than normal background risks might be shown to have higher increases in risk attributable to radiation, depending on the form of interaction between radiation exposures and these other cancer risk factors.

It is not scientifically supportable or feasible to adjust NIOSH–IREP risk models for the multitude of occupational and community exposures. The carcinogenic risks associated with most chemical exposures, and the appropriate form of their interaction with radiation, have not been adequately quantified. Moreover, DOL generally would not have access to exposure data on the individual's exposure to chemicals or radiation in the community. As discussed above, access to data on occupational exposures to chemicals is also infeasible at this time.

F. Covered Exposures

A few commenters recommended changes in the set of exposures included by this rule to contribute to the probability of causation calculation.

Several commenters recommended against HHS including medical screening x rays administered to nuclear weapons employees as a condition of employment. Similar comments were received on the interim final HHS dose reconstruction rule (42 CFR 82) as well. Commenters argue that the benefit of these exposures justifies their attendant risks, and therefore they should not contribute to the acceptance of a claim for compensation.

HHS will not exclude radiation exposures resulting from these occupationally required medical screening x rays. The important factor in this decision is that the exposures were incurred ''in the performance of duty,'' as specified by EEOICPA. The employees were required to receive these x ray screenings and hence were exposed to radiation in performing this duty.

Several commenters recommended HHS include cancer risks associated with chemical exposures and in effect calculate a probability of causation related to all occupational exposures, rather than radiation exposures alone.

HHS cannot include the cancer risks associated with chemical exposures in the calculation of probability of causation. EEOICPA explicitly limits these guidelines and DOL to making determinations as to whether the cancer subject to a claim was caused by radiation doses incurred in the performance of duty (see § 7384(n)(c) of EEOICPA).

G. Covered Illnesses

HHS received several comments addressing the exclusion or inclusion of illnesses covered by these guidelines.

Several commenters noted that EEOICPA only covers cancers but should cover other or all illnesses. A second commenter recommended that probability of causation should be determined for inherited genetic effects (among offspring of covered workers).

The probability of causation guidelines cover only cancers because this is a statutory requirement of EEOICPA (see discussion of statutory requirements above). Moreover, science has not progressed sufficiently to permit probability of causation determinations for many radiogenic illnesses other than cancers; specifically not for inherited genetic effects.

Readers should note, however, that part B of EEOICPA, which provides lump sum payments of $150,000 as well as medical benefits, provides coverage for chronic beryllium disease and silicosis (when incurred by workers exposed in connection with mining of tunnels for atomic weapons tests or experiments in Nevada or Alaska), two well documented occupational illnesses. Part B also provides for medical monitoring of covered workers with beryllium sensitivity. In addition, part D of EEOICPA provides assistance through a worker advocacy program administered by DOE to assist nuclear

weapons workers with illnesses that might have resulted from toxic occupational exposures who are seeking state workers' compensation benefits. Panels of expert physicians appointed by HHS will review the medical records in connection with each of these cases and make a determination as to whether the illness was likely to have been caused by toxic occupational exposures.

Another commenter recommended that HHS not permit probability of causation to be determined for cancers in situ—that is, cancers that have yet to spread to neighboring tissues. In other words, the comment recommends assigning a probability of causation of zero to individuals with this early stage of cancer.

HHS is retaining the procedures it proposed for estimating probability of causation for carcinomas in situ, treating them within NIOSH–IREP identically to invasive cancers. Although more research is needed, some studies have shown the risk factors for a carcinoma in situ are similar to cancer at a later stage. In addition, for any given individual, it is not possible to determine which carcinomas in situ will progress to become invasive cancers.

H. Radiation Dose Threshold for Calculating Probability of Causation

Several commenters recommended HHS establish a radiation dose threshold below which DOL would deny the claim without calculating probability of causation. One commenter proposed NIOSH–IREP be modified to take into account alternative theories of radiation effects at low cumulative doses. The commenters argue that it is unknown whether cancers can be caused at radiation doses below 10 to 20 rem. In addition, several commenters note that claims for rare cancers, for which there is likely to be a high level of uncertainty about the dose-risk relationship, would have unfair advantage over claims for more common cancers, due to the use of the 99 percent credibility limit.

The National Research Council, which reviewed IREP, noted concern about the effect of uncertainty with respect to rare cancers. NCI has responded to this concern by grouping rare cancers in more general cancer categories, for which there is a more robust research basis for quantifying risk.

HHS does not find that any further measures are necessary, particularly the application of a threshold. The issue of whether or not there is a threshold for causation of cancer by radiation is controversial. Moreover, the issue is avoided by the practical approach taken in this rule. Doses resulting in a probability of causation finding of 50 percent or greater are determined based on current and cumulative epidemiologic findings. The NCI solution of grouping rare cancers addresses the concern about high levels of uncertainty for rare cancers.

I. Non-Radiogenic Cancers

One commenter recommended against the proposed rule's consideration of chronic lymphocytic leukemia (CLL) as non-radiogenic (§ 81.30). This provision requires DOL to assign a probability of causation of zero for a claim for CLL. The commenter asserts that it cannot be proven that this form of leukemia is non-radiogenic.

As discussed in the notice of proposed rulemaking and below, CLL is widely considered non-radiogenic by the radiation health research community and is not covered by other radiation compensation programs. Moreover, there is no risk model appropriate to CLL, nor data to support the development of such a risk model. Consequently, it is not possible to calculate probability of causation for CLL and it is both appropriate and necessary to consider CLL as non-radiogenic for the purposes of this rule.

J. Documentation of NIOSH–IREP

Several commenters recommended NIOSH fully document the risk models and calculations of NIOSH–IREP so that the basis for its calculations are fully transparent. One commenter added that in this documentation, NIOSH should explain how different sources of uncertainty are taken into account.

NIOSH agrees with the comment and, as indicated in the notice of proposed rulemaking, is committed to maintaining and providing full documentation on NIOSH–IREP. To a substantial extent, this documentation is directly available to the public while using or examining NIOSH–IREP. The software, which is accessible for public use from the NIOSH homepage on the internet, has a feature that allows the user to call-up the formulae and information underlying each calculation. The user can also call-up graphic illustrations (pie charts) that quantitatively depict the role of different sources of uncertainty in contributing to the overall uncertainty calculated for use in a probability of causation estimate. [15] As noted above, the documentation is also available in print form by contacting NIOSH.

K. Current Technical Elements of NIOSH–IREP

HHS received a variety of comments on specific aspects of the cancer risk models in NIOSH–IREP. While these risk models are not themselves subject to this rulemaking, HHS is committed to receiving and responding to public comments on NIOSH–IREP, and making improvements as appropriate. As indicated in § 81.12 of this rule, recommendations for modifications to NIOSH–IREP will be addressed routinely through a public process involving the Advisory Board on Radiation and Worker Health. Hence, HHS addresses current comments submitted during the rulemaking comment period below, but notes that some of these issues may receive further consideration subsequent to this rulemaking, once HHS has obtained advice on these issues by the Advisory Board. The Advisory Board has received these public comments for review.

One commenter generically recommended against making use in NIOSH–IREP of cancer risk models developed for determining probability of causation for atomic veterans. As discussed above and in the notice of proposed rulemaking, most of the risk models in IREP were developed based on the exposure and disease experience of Japanese survivors of the atomic bomb detonations in World War II. The commenter finds the differences between the exposure conditions of these survivors and those of nuclear weapons employees too great to support probability of causation determinations for the latter.

HHS recognizes the substantial differences between the radiation exposure experiences of these two populations and discussed these differences above and in the notice of proposed rulemaking. To address these differences, NIOSH has adapted the available risk models to the extent feasible and supportable using current science. The difference in exposure characteristics is also part of the rationale for the provisions of this rule supporting updates of NIOSH–IREP, as scientific progress allows additional improvements. One of the specified goals of such updates is to use, as this becomes feasible, risk findings derived from occupational health studies of nuclear weapons workers.

Nonetheless, NIOSH maintains that the current scientific basis applied in

[15] The uncertainty distributions for the various sources of uncertainty involved in a probability of causation estimate are combined in NIOSH–IREP using a Monte Carlo simulation program that draws values randomly, repeatedly from each distribution to derive a single, representative uncertainty distribution.

NIOSH–IREP is the best available at this time and that its use is both reasonable and fair. As discussed throughout this rule, NIOSH has taken into account, whenever feasible, recognized limitations in the current state of relevant sciences.

Several commenters recommended changes in the way the lung cancer risk model adjusts risk according to the individual's smoking history. The risk model produces a higher probability of causation that lung cancer was caused by radiation for a non-smoker than a smoker, at a given level and pattern of radiation exposure.

One commenter indicated that the probability of causation estimate for a heavy smoker should be much lower than currently estimated by the risk model. The other commenters recommended the opposite, that NIOSH should eliminate adjustment for smoking history. They assert research indicates that smoking may have a multiplicative effect on lung cancer risk, when combined with radiation exposure. If this research were proven correct, then smoking history would not affect the contribution of radiation to cancer risk, and could indeed be omitted from consideration.

The adjustment for smoking history in NIOSH–IREP has been adopted from the approach developed by NCI, and fully takes into account the cumulative body of research evaluating the interaction between smoking and radiation risks, as well as leading scientific views on this research. The NCI review of relevant literature, and a scientific consensus panel opinion (UNSCEAR 2000 [16]), conclude that the best-supported risk models to evaluate the form of interaction between smoking and radiation are based on meta-analyses of radon-exposed workers. Combined analyses of these studies suggest that the most appropriate form of interaction is sub-multiplicative (i.e., the excess relative risk from radiation exposure among smokers is less than the excess relative risk among non-smokers), but greater than additive (Lubin and Steindorf 1995). NCI used this scientific basis to develop an uncertainty distribution for the form of interaction between smoking and radiation in the lung cancer risk models that is centered on a sub-multiplicative model (i.e., a model which assumes the excess relative risk of cancer per unit of radiation dose is lower for individuals who smoke more), but includes the possibility of either a multiplicative model (i.e., that excess relative risk per unit of radiation dose is the same for various levels of smoking, including non-smokers) or a super-multiplicative model (i.e., that excess relative risk per unit dose is higher for individuals who smoke more). As with all assumptions, this uncertainty distribution is subject to modification in future revisions of NIOSH–IREP, pending the availability of new scientific information.

Several commenters recommended against use of a factor that reduces cancer risk for workers who were exposed to radiation at older ages. In support of this recommendation, they contend atomic bomb survivor and occupational studies do not find an inverse relationship for adults between age at time of radiation exposure and cancer risk.

NIOSH is using in NIOSH–IREP the NCI approach to adjusting radiation risk estimates for different exposure ages. This approach is based on new epidemiological analyses of atomic bomb survivors who were of working age when exposed during the blast, and uses an approach recommended by an international expert committee (Pierce et al. 1993, UNSCEAR 2000 [17]). It addresses all solid cancers except skin and thyroid. Thus, for most cancers NIOSH–IREP relies on direct evidence from the A-bomb survivors exposed as adults rather than as children. NCI did not incorporate any age at exposure effect for the following cancers: acute myeloid leukemia, chronic myeloid leukemia, lung cancer (non-radon exposures), and female genital cancers other than ovary. The NCI models do incorporate a trend of decreasing risk per unit dose with increasing age at exposure for the following cancer sites: acute lymphocytic leukemia, all leukemia other than chronic lymphocytic, basal cell carcinoma, and cancers of thyroid. For radon exposures and lung cancer, there is no direct adjustment for exposure age: risks are dependent on time since last exposure and on age at diagnosis. The effect of this adjustment is that, at a constant ''time since last exposure'', the risk decreases for increasing age at last exposure; however, for constant ''age at diagnosis'', the risk increases for increasing age at last exposure. For all other cancers, the NCI models incorporate a trend of decreasing risk per unit dose for exposure ages between 15 and 30, and assume constancy (no effect of age) thereafter.

There is substantial evidence from several key studies in addition to those of the A-bomb cohort that suggests radiation risk for many cancers decreases with increasing age at exposure. These include studies of breast cancer among x-ray tuberculosis patients (Boice et al. 1991 [18]), of thyroid cancer among medically- and occupationally-exposed populations (summarized in UNSCEAR 2000a3), and of skin cancer (UNSCEAR 2000b3). While some studies of DOE workers suggest no effect or find increased relative risk estimates for certain cancers from exposure to radiation at older ages, this information is insufficient to support the selection of appropriate cancers and an appropriate method for quantitatively incorporating this information into risk adjustments in NIOSH–IREP. As indicated in the rule, HHS will re-evaluate this issue in future revisions of NIOSH–IREP, as warranted by advances in scientific information.

Several commenters recommended adding a risk adjustment factor to NIOSH–IREP to account for a possible ''healthy survivor effect'' presently unaccounted for in the research on Japanese atomic bomb survivors. The theory underlying this comment is that atomic bomb survivors may be healthier than the general public and less likely to incur cancer. Therefore, according to this theory, it would be mistaken to equate the level of increased cancer risk from radiation among this robustly healthy population to the level of increased cancer risk among the U.S. population, with its normal distribution of health. If this were proven correct, the risk models in NIOSH–IREP should

[16] United National Scientific Committee on the Effects of Atomic Radiation. 2000. Sources and Effects of Ionizing Radiation: UNSCEAR 2000 Report to the General Assembly, with Scientific Annexes, Volume II: Effects; p. 201–203.

Lubin JH and Steindorf K. 1995. Cigarette use and the estimation of lung cancer attributable to radon in the United States. Radiat. Res. 141:79–85.

[17] Pierce DA, Preston DL. 1993. Joint analysis of site-specific cancer risks for the A-bomb survivors. Radiat. Res. 137:134–142.

United National Scientific Committee on the Effects of Atomic Radiation. 2000. Sources and Effects of Ionizing Radiation: UNSCEAR 2000 Report to the General Assembly, with Scientific Annexes, Volume II: Effects; p. 208.

SU> Lubin JH, Boice JD Jr, Edling C, et al. 1995. Lung cancer risk in radon-exposed miners and estimation of risk from indoor exposure. J. Natl. Canc. Inst. 87≅817–827.

Boice JD Jr, Engholm G, Kleinerman RA, et al. 1991. Frequent chest x-ray fluoroscopy and breast cancer incidence among tuberculosis patients in Massachusetts. Radiat. Res. 125:214–222.

United National Scientific Committee on the Effects of Atomic Radiation. 2000a. Sources and Effects of Ionizing Radiation: UNSCEAR 2000 Report to the General Assembly, with Scientific Annexes, Volume II: Effects; p. 338–343.

United National Scientific Committee on the Effects of Atomic Radiation. 2000b. Sources and Effects of Ionizing Radiation: UNSCEAR 2000 Report to the General Assembly, with Scientific Annexes, Volume II: Effects; p. 402.

Richardson DB, Wing S, Hoffmann W. 2001. Cancer risk from low-level ionizing radiation: the role of age at exposure. Occupat. Med.: State of the Art Reviews 16:191–218.

be adjusted to increase the level of cancer risk caused by a unit of radiation dose, since the U.S. population would presumably be more susceptible than the Japanese survivor population to the cancer-causing effects of radiation.

The possible existence of a healthy survivor effect has been theorized by some researchers (Stewart and Kneale 1990 [19]), and has been determined by others to be of small magnitude or non-existent (Little and Charles 1990, NCRP 1997). The NCI determined that insufficient information on the possible effect of this bias is available for use the IREP program. NIOSH, in consultation with the Advisory Board on Radiation and Worker Health, will consider whether to add an adjustment factor to future versions of NIOSH–IREP to account for a possible healthy survivor effect, if supported by new scientific information. HHS notes such a finding would be equally relevant for claimants under EEOICPA and under the Atomic Veterans Compensation Program, and thus should be decided by scientific consensus between these two programs whose relevant policies are both determined by HHS.

Several commenters recommended changing the factor in NIOSH–IREP that reduces cancer risk for workers who were exposed to low linear energy transfer (LET) [20] radiation at low dose rates (workers who received many small doses of radiation, versus fewer large doses). They cite reports by the Nuclear Regulatory Commission and the International Agency for Research on Cancer as finding no relationship between the rate at which low LET radiation doses are incurred and the risk of cancer.

HHS agrees that this is an area of substantial uncertainty. Many studies suggest that risks are reduced for particular cancers when doses are fractionated or received at low dose-rate, while other studies suggest no effect of dose-rate or dose fractionation on radiation risk.

NIOSH–IREP accounts for this uncertainty. For chronic exposures, NIOSH–IREP adopts the approach used in the final revision of the NCI–IREP program, which more heavily weights a probability that there is no attenuation of risk at low dose rates of exposure. This uncertainty distribution also includes a small probability that dose-rate reduction or dose fractionation enhances, rather than reduces, radiation risk.

One commenter recommends that NIOSH–IREP account for a possible inverse relationship between exposure to low doses of high LET radiation and cancer risk. The commenter cites recent research suggesting that individuals who incurred high LET radiation doses at lower rates had higher risk of cancer, compared with individuals who incurred the same cumulative doses at higher rates.

As indicated in the notice of proposed rulemaking and above, NIOSH has incorporated the possibility of this inverse relationship into NIOSH–IREP for both neutron and low-LET exposures. Based on reviews of subject matter experts, the revised version of NIOSH–IREP includes a small probability of an inverse dose-rate effect for alpha radiation exposures as well.

One commenter noted that a linear-quadratic model of the dose-risk relationship is not equivalent to use of a dose-rate correction factor to reduce the per-unit contribution of low doses to cumulative risk of cancer. The commenter recommended either using a dose-rate correction factor to keep these model elements separate, or alternatively to explain why it is appropriate to use the linear-quadratic model to mimic a reduced cancer risk effect at low dose rates.

This comment is contradicted by several research groups, including the NCI–IREP working group, the NIH Ad Hoc Working Group which initially developed the Radioepidemiological Tables (NIH 1985 [21]), and the Committee on Biological Effects of Ionizing Radiation (BEIR)V. The BEIR V committee explicitly states that ''[Dose rate] reductions should be applied only to the non-leukemia risks, as the leukemia risks already contain an implicit DREF [dose rate effectiveness factor] owing to the use of the linear-quadratic model'' [22]. The theoretical basis for this equivalence is the observation that the use of a linear-quadratic dose assumption applies a reduction in risk that is equivalent to using a dose-and-dose-rate reduction factor of about two, which has been commonly recommended by advisory groups for modeling leukemia risk.

One commenter recommended NIOSH change the dose and dose rate effectiveness factor (DDREF) for leukemia (for low LET radiation exposure) to three. This would reduce by two-thirds the probability of causation estimates for workers with leukemia who accrued their cumulative radiation doses slowly. The commenter cites two studies to support this recommendation.

NIOSH–IREP uses the models developed by the NCI Working Group for leukemia risk from low-LET exposure. As discussed previously, rather than incorporating a DDREF of greater than one for leukemia risk models, the dose-response function for leukemia is of the linear-quadratic form. This corresponds approximately to a DDREF of two for leukemia risk at low compared to high doses and dose rates. This approach has been recommended by several expert committees, referenced above. [6, 7] While findings from individual epidemiological studies may vary from this approach, these individual study findings are subject to the limitations of the studies. For this reason, risk modeling requires consideration of the totality of scientific evidence regarding the effects of dose protraction. Consistent with the extensive expert analyses cited above, NIOSH–IREP uses a linear-quadratic model with uncertainty in the model parameters, which best captures the uncertainties associated with the effects at low doses and dose rates.

One commenter recommends NIOSH obtain peer review for the radiation weighting factors used in NIOSH–IREP. These weighting factors take into account the differing biological effect potency of different types of radiation in inducing cancer. The commenter states that a factor of 40 used for alpha radiation in NIOSH–IREP, that this is ''too conservative'' (i.e., results in probability of causation estimates that would be higher than scientifically justified), and notes that the International Commission on Radiological Protection (ICRP) intends to lower its recommended weight for alpha radiation from 20 to 10.

The commenter misunderstands how information on the biological effectiveness of radiation types is used in NIOSH–IREP. The ICRP and other leading expert groups recommend weighting factors in the form of point estimates to summarize the differing biological effectiveness of various types of radiation for use by radiation protection programs. These programs

[19] Stewart AM, and Kneale GW. 1990. A-bomb radiation and evidence of late effects other than cancer. Health Phys. 58:729–735.

Little MP, and Charles MW. 1990. Bomb survivor selection and consequences for estimates of population cancer risks. Health Phys. 59:765–775.

National Council on Radiation Protection and Measurements (NCRP). 1997. Uncertainties in fatal cancer risk estimates used in radiation protection. NCRP report 126. 112 pp.

[20] See § 81.4 in rule for a definition of LET.

[21] National Institutes of Health (NIH). 1985. Report of the National Institutes of Health Ad Hoc Working Group to Develop Radioepidemiological Tables. US DHHS. NIH Publication No. 85–2748, p. 88.

[22] National Research Council. 1990. Health Effects of Exposure to Low Levels of Ionizing Radiation: BEIR V. National Academy Press, Washington, DC. 421 pp., p.174.

require a point estimate to calculate appropriate safety criteria that can be applied to protect populations. On the other hand, the task involving NIOSH–IREP is to calculate probability of causation for individual claims, taking into account sources of scientific uncertainty. There is substantial uncertainty of science in describing the biological effectiveness of various types of radiation, and in part due to this uncertainty, there are differences in the review findings of ICRP, the International Commission on Radiation Units and Measurements, and the National Council on Radiation Protection and Measurements. In addition, some radiation exposures are incompletely addressed by the reviews by these expert groups.

To evaluate scientific uncertainty, NIOSH analyzed the reviews of biological effectiveness of radiation by each of the expert committees cited above and, where these reviews were incomplete, other expert reviews and primary research as well. Based on this analysis, NIOSH established the central tendency of ''relative biological effectiveness'' for each type of radiation and assigned a probability distribution to describe the scientific uncertainty about the central tendency estimate. To calculate probability of causation, NIOSH–IREP will apply these resulting uncertainty distributions derived by NIOSH, instead of point estimate weighting factors, to account for the differing biological effectiveness of various radiation types.

The NIOSH analysis of relative biological effectiveness described here has been summarized in a scientific paper, peer-reviewed by subject matter experts, and revised accordingly. It is available to the public, along with the peer-review comments, from the NIOSH homepage on the internet or by direct request to NIOSH (addresses provided above) [23].

One commenter questions how the lung cancer model for radon in NIOSH–IREP compares with the recommendations of the Committee on Health Risks of Exposure to Radon (BEIR VI) [24].

As discussed in the notice of proposed rulemaking and above, the lung cancer model for radon in NIOSH–IREP was developed based on an analysis of risk by the Radiation Exposure Compensation Act (RECA) Committee [25], as recommended by the National Research Council review of the NCI IREP software. The RECA committee recommended scientific methods for adapting the radon and lung cancer risk models derived from uranium miner research to compensation decisions. These research findings were an important component of the BEIR VI analyses as well.

L. HHS Dose Reconstruction Program (42 CFR 82)

HHS received several comments addressed to this rule that relate to HHS dose reconstructions under EEOICPA. In some cases, the comments were directed to this rule because dose reconstruction results serve as inputs to calculate probability of causation. The HHS rule establishing methods for dose reconstruction, 42 CFR Part 82, is being published simultaneously in this issue of the **Federal Register**.

Several commenters recommended that these guidelines prescribe the selection of uncertainty distributions associated with radiation dose information supplied by the NIOSH dose reconstruction.

As discussed in the dose reconstruction rule, uncertainty distributions associated with the dose information will indeed be defined by NIOSH in its individual dose reconstruction final reports provided to DOL, the claimant, and DOE. This information, also included in the electronic dose files provided to DOL by NIOSH, will be imported into NIOSH–IREP by DOL when it calculates probability of causation.

These uncertainty distributions associated with dose information cannot be generically prescribed by these guidelines. This information will vary substantially depending on radiation exposure circumstances and informational sources associated with each claim. Therefore, NIOSH will be defining the use of appropriate uncertainty distributions on a claim-by-claim basis, based on technical procedures established by NIOSH to implement the HHS dose reconstruction rule.

One commenter recommended NIOSH use a default assumption that characterizes radiation doses as chronic rather than acute. The commenter indicated that the radiation doses incurred by many workers are more accurately characterized as chronic using traditional definitions.

NIOSH will characterize radiation doses as chronic when it has information to substantiate this designation. However, in most cases NIOSH is unlikely to have sufficient information to make this distinction. For these cases, NIOSH will continue to characterize doses as acute as the default assumption, since this gives claimants the benefit of the doubt. As discussed above, this rule, consistent with the requirement of EEOICPA to calculate probability of causation at the upper 99 percent credibility limit, gives claimants the benefit of the doubt with respect to uncertainty. The use of chronic as a default assumption would reduce the level of probability of causation calculated for some claims.

One commenter recommended NIOSH–IREP include as an input radiation doses from nuclides (types of radiation) associated with particle accelerators.

The radiation weighting factors included in NIOSH–IREP cover the vast majority of exposures that have occurred or will occur in the claimant population. Exposures to the most unusual radiation exposure types, such as protons and other accelerator produced particles, will be addressed on an individual basis, as specified by NIOSH. It would not be useful to construct a priori probability distributions for these radiation types without knowledge of the range of energies likely to be involved in an actual exposure. Probability distributions developed for these unusual radiation types will be incorporated into the probability of causation calculation for affected claimants by DOL through a user-definable feature of NIOSH–IREP. NIOSH will define the probability distribution to be applied by DOL and summarize its technical basis in the dose reconstruction report.

One commenter questioned how NIOSH would know the energies of neutron doses, since this information will not always be available from DOE or AWE records.

As discussed in the interim final and final dose reconstruction rules, NIOSH will assign the energies for claims in which this specific information is unknown. NIOSH will give the benefit of the doubt to the claimant in making such assignments, such that the energy selected is consistent with available information and represents the case most favorable to the claimant for calculating probability of causation.

[23] The paper was originally titled: ''Proposed Radiation Weighting Factors for Use in Calculating Probability of Causation for Cancers'' and is now published with revisions and more extensive explanation under the title: ''Relative Biological Effectiveness Factors (RBE) for Use in Calculating Probability of Causation of Radiogenic Cancers.''

[24] National Research Council. 1999. Health Effects of Exposure to Radon: BEIR VI. National Academy Press, Washington, DC. 500 pp.

[25] Final Report of the Radiation Exposure Compensation Act Committee, submitted to the Human Radiation Interagency Working Group, July 1996 (Appendix A), 30 pp (plus Figures).

One commenter recommended that NIOSH combine the internal and external dose reconstruction data into single annual dose values.

It is unclear how this suggested change would be useful. Moreover, it would rarely be feasible. It would be feasible only when radiation doses in a given year are limited to a single type of radiation and the uncertainty distributions for the external and internal doses are identical.

Several commenters questioned why HHS added a parameter to the definition of ''covered employee,'' under § 81.4 of the proposed rule, that is not specified in EEOICPA. HHS specified more narrowly than EEOICPA that a covered employee, for the purposes of the HHS rules, is a DOE or AWE employee for whom DOL has requested HHS perform a dose reconstruction.

This distinction results practically from the separate responsibilities of DOL and HHS in implementing EEOICPA. DOL is solely responsible for initially reviewing each claim, evaluating whether the claim represents a covered employee with a covered illness, and determining whether or not the claim requires a dose reconstruction. The only claims DOL will forward to HHS for dose reconstructions are those involving a covered employee with a cancer not covered by provisions of the Special Exposure Cohort. Hence, HHS retains its proposed definition in this rule to be clear that NIOSH will only conduct dose reconstructions under EEOICPA for the subset of claims submitted by DOL to HHS for dose reconstructions. This is intended to avoid the possible confusion and delay that would arise if claimants or the public were to directly submit to NIOSH requests for dose reconstructions.

M. Special Exposure Cohort

HHS received several comments that provide recommendations, criteria, or concerns related to adding members to the Special Exposure Cohort established under EEOICPA. These comments fall outside the scope of this rule and address related but separate procedures to be established by HHS.

As discussed above, HHS is proposing procedures by which it will consider petitions by classes of employees at DOE or AWE facilities to be added to the cohort, with the advice of the Advisory Board on Radiation and Worker Health. These procedures will be published soon in the **Federal Register**. The proposed HHS procedures and their accompanying explanation address the comments received and directly solicit additional public comments, which HHS will fully consider in establishing final procedures.

N. DOL Responsibilities Under EEOICPA

HHS received several comments that relate to DOL responsibilities under EEOICPA and thus fall outside the scope of this rule.

One commenter recommended that claimants be provided with full documentation of the basis for the probability of causation estimate determined for their claim by DOL.

DOL will provide the claimant with a recommended decision which will explain the decision based upon the probability of causation. In addition, NIOSH will provide the claimant with complete documentation on the dose reconstruction conducted for the claim, which, together with the DOL report, provides the claimant with a complete set of the claim-related data and information used to calculate probability of causation.

The claimant would not, however, automatically receive documentation of the formulae and underlying research basis for the cancer risk models applied to the claim in NIOSH–IREP. This information is highly technical and complex and is unlikely to be of value to most claimants. Claimants who desire this information, however, can obtain it either from NIOSH–IREP, from the NIOSH homepage, or by contacting NIOSH directly (see contact information above). Some details of IREP documentation are only available at this time from NCI but will be incorporated into NIOSH informational resources as soon as possible.

One commenter recommended that claimants be permitted to submit affidavits in lieu of medical records when necessary.

DOL determines what types of information can constitute medical evidence of a diagnosis of cancer (see 20 CFR 30.211.). More details can be obtained by contacting DOL.

One commenter recommended that staff working for contractor support services offsite from the DOE facility should be treated as covered employees under EEOICPA. The comment identifies workers providing offsite laundry services as an example of such support staff. As discussed above, DOL is responsible for determining whether an individual is a covered employee within the scope of coverage defined by Congress in EEOICPA. Individuals who are concerned that certain employee groups involved in nuclear weapons production or related activities might be excluded from coverage under EEOICPA should consult DOL, which makes these determinations.

III. Review and Recommendations of the Advisory Board on Radiation and Worker Health

As discussed above, the Advisory Board on Radiation and Worker Health is required by Section 7384(n)(c) of EEOICPA to conduct a technical review of these HHS guidelines. The Board reviewed the guidelines during public meetings on January 22–23 and February 5, 2002. In preparation for the meeting, the Board members individually reviewed the notice of proposed rulemaking as well as the HHS interim final rule providing the methods of dose reconstruction (42 CFR 82) that govern the estimation of radiation doses to be used under these guidelines. The members also reviewed public comments on these rules and written comments by subject matter experts who evaluated technical elements of NIOSH–IREP. In addition, NIOSH staff members gave formal presentations on the HHS rules, implementation procedures, and related issues during the Board meetings. The transcripts and minutes of these meetings are included in the NIOSH docket for this rule and are available to the public.

All of the Board members participated in the technical review of these guidelines and they unanimously concurred in establishing the Board findings and recommendations. The Board organized its findings and recommendations to correspond with the three general questions for public comment HHS identified in the notice for proposed rulemaking. The findings and recommendations are provided below, together with responses by HHS to the recommendations:

Board Comment #1: The Board agrees that the NIOSH guidelines and procedures for probability of causation determinations have been developed using the best and most current scientific information relating radiation exposures to cancer risks. The use of current recommendations from independent expert bodies lends strength to the approach proposed by NIOSH. The NIOSH approach also implements the spirit of concern for nuclear workers that was inherent in the legislation underlying this compensation program. In this context, the NIOSH guidelines and procedures provide an appropriate application of existing science to the compensation process.

HHS Response: No response is necessary, but it may be helpful to readers to explain the Board's reference to the ''spirit of concern.'' HHS has

implemented the ''spirit of concern'' to which the Board refers by consistently and reasonably giving the benefit of the doubt to nuclear weapons workers, whenever feasible, with respect to policy decisions and technical procedures involving factual or scientific unknowns and uncertainty.

Board Comment #2: ''The Board has also noted the differences between the approach being used in this compensation program and that of the Atomic Veterans Act. There are significant differences in the categories of compensation covered by the two acts. In some cases, the Atomic Veterans Act required primarily that the claimants were present in a specific area, had one of the specified cancers, and were therefore compensated. This proposed rule is an effort to address much more complicated situations and to face the reality that simple exposure to radiation does not automatically presume the development of disease. The Board recognizes the excellent efforts of NIOSH staff and their subject matter experts in bringing the best known current science to an appropriate method for translating experience gained in the veterans exposure calculations to this civilian nuclear worker proposal.''

HHS Response: No response necessary.

Board Comment #3: ''The Board also agrees that the proposed NIOSH procedures appropriately allow for the incorporation of new scientific information into the compensation procedures as this new information becomes available. However, given the limited time that the Board has had to review the details of the probability of causation procedures and the potential impact of changes in the NIOSH IREP on compensation decisions, the Board recommends that the regulations be amended to formalize the role of the Board in reviewing any substantial changes in these procedures (i.e., the NIOSH IREP). This change should include publication of the planned changes in the **Federal Register**, an appropriate opportunity for public comment, and then review by this Board before finalization. Although these actions are included in the Preamble ''Background,'' (Section III, Subsection I, Paragraph 3) of 42 CFR Part 81, making them part of the rule itself would formalize the updating process, significantly strengthening assurance that review of revisions by the Board will occur.''

HHS Response: HHS accepts this recommendation by the Board. Accordingly, as discussed above in response to public comments on peer-review, HHS has moved provisions for peer-review involving the Board from the preamble of the notice of proposed rulemaking into the body of the rule itself. These provisions can be found at 42 CFR 81.12.

IV. Summary of the Rule

Congress, in enacting EEOICPA, created a new Energy Employees Occupational Illness Compensation Program to ensure an efficient, uniform, and adequate compensation system for certain employees. Through Executive Order 13179, the President assigned primary responsibility for administering the program to DOL. The President assigned various technical responsibilities for policymaking and assistance to HHS. Included among these is promulgation of this rule to establish guidelines DOL will apply to adjudicate cancer claims for covered employees seeking compensation for cancer, other than as members of the Special Exposure Cohort seeking compensation for a specified cancer. Sections 81.20–81.25 and 81.30 provide guidelines for determining the probability of causation with respect to all known cancers.

In the summary below, HHS indicates all the changes in provisions of this rule made since the notice of proposed rulemaking. These occur under §§ 81.10(b) and 81.12.

Introduction

Sections 81.0 and 81.1 briefly describe how this rule relates to DOL authorities under EEOICPA and the assignment of authority for this rule to HHS. Section 81.2 summarizes the specific provisions of EEOICPA directing HHS in the development of this rule.

Definitions

This section of the regulation defines the principal terms used in this part. It includes terms specifically defined in EEOICPA that, for the convenience of the reader of this part, are repeated in this section. The citation to EEOICPA has been revised to reflect the codification of the Act in the United States Code.

Data Required To Estimate Probability of Causation

Sections 81.5 and 81.6 identify the sources and types of personal, medical, and radiation dose information that would be required by this regulation. Claimants will provide personal and medical information to DOL under DOL regulations 20 CFR Part 30. NIOSH will provide radiation dose information pursuant to 20 CFR Part 30. NIOSH will develop the dose information required pursuant to the HHS regulation under 42 CFR Part 82, which was promulgated on October 5, 2001 as an interim final rule and is being promulgated as a final rule simultaneously with this final rule in this issue of the **Federal Register**. The application of this personal, medical, and radiation dose information to estimate probability of causation is described generally under §§ 81.22—81.25.

Requirements for Risk Models Used To Estimate Probability of Causation

Sections 81.10 and 81.11 describe the use of cancer risk models and uncertainty analysis underlying the NIH RadioEpidemiological Tables in their current, updated form, which is a software program named the ''Interactive RadioEpidemiological Program'' (IREP). NIOSH–IREP, the version of IREP to be used by DOL to implement this rule, is discussed extensively in the notice of proposed rulemaking and above. These sections also propose criteria by which the risk models in NIOSH–IREP may be changed to ensure that probability of causation estimates calculated for EEOICPA claimants represent the unique exposure and disease experiences of employees covered by EEOICPA. In response to public comments, a criterion discussed above has been added to § 81.10. This criterion authorizes NIOSH to modify NIOSH–IREP to account for new understanding of the potential interaction between cancer risks associated with occupational exposures to chemical carcinogens and radiation-related cancer effects (see § 81.10(b)(4)).

Section 81.12 was added in response to comments and describes the procedure to update NIOSH–IREP. NIOSH may periodically revise NIOSH–IREP to add, modify, or replace cancer risk models, improve the modeling of uncertainty, and improve the functionality and user-interface of NIOSH–IREP. Principal sources of potential improvements in cancer risk models include new epidemiologic research on DOE employee populations and periodic updates from scientific committees evaluating such research (e.g., the Committee on Biological Effects of Ionizing Radiation).

Improvements may also be recommended by the Advisory Board on Radiation and Worker Health, scientific reviews relevant to or addressing this program, public comment, or by DOL, which is the principal user and hence may require functional changes and improvements in the user-interface.

Substantive changes to NIOSH–IREP (changes that would substantially affect

estimates of probability of causation calculated using NIOSH–IREP, including the addition of new cancer risk models) will be submitted to the Advisory Board on Radiation and Worker Health for review. Proposed changes provided to the Advisory Board for review will also be made available to the public, which will have opportunity to comment and have its comments considered by NIOSH and the Board.

To facilitate public participation in updating NIOSH–IREP, NIOSH will periodically publish a notice in the **Federal Register** informing the public of proposed substantive changes to NIOSH–IREP currently under development, the status of the proposed changes, and the expected completion dates. NIOSH will also publish a notice in the **Federal Register** notifying DOL and the public of the completion of substantive changes to NIOSH–IREP. In the notice, NIOSH will address relevant public comments and recommendations from the Advisory Board received by NIOSH.

Guidelines To Estimate Probability of Causation

Sections 81.20 and 81.21 require DOL to use NIOSH–IREP to estimate probability of causation for cancers for which probability of causation estimates can be calculated using available cancer risk models. Section 81.21 also requires DOL to assume carcinoma in situ (ICD–9 [26] codes 230–234), neoplasms of uncertain behavior (ICD–9 codes 235–238), and neoplasms of unspecified nature (ICD–9 code 239) are malignant, for purposes of estimating probability of causation.

Sections 81.22–81.25 provide general guidelines for the use of NIOSH–IREP and specific applications to accommodate special circumstances anticipated. The special circumstances include claims in which: (1) The primary site of a metastasized cancer is unknown; (2) the subtype of leukemia presented lacks a single, optimal risk model in NIOSH–IREP; and (3) two or more primary cancers are presented, requiring further statistical adjustment of probability of causation estimates calculated using NIOSH–IREP.

The procedure concerning subtypes of leukemia (2) is needed because of a limitation of the data on Japanese atomic bomb survivors, as discussed above and in the notice of proposed rulemaking. The general leukemia model in IREP allows for adjustment for age at exposure, which is an important modifier of leukemia risk. The data are too sparse, however, to allow for such an adjustment with respect to specific types of leukemia, with the exception of chronic myeloid leukemia. Since it is not possible to determine which factor, age at exposure or leukemia subtype, is more important to determining probability of causation for most specific types of leukemia, the guidelines require use of both the general model and the specific model. The guidelines require DOL to use the findings of whichever model produces the higher probability of causation estimate.

Section 81.30 specifies one cancer to be considered non-radiogenic for the purposes of this rule: chronic lymphocytic leukemia (ICD–9 Code: 204.1). DOL would assign a value of zero to the probability of causation for a claim based on this type of leukemia. There is general consensus among the scientific and medical communities that treatment of this leukemia as non-radiogenic is appropriate, and such treatment is consistent with other radiation illness compensation programs.

V. Significant Regulatory Action (Executive Order 12866)

This rule is a ''significant regulatory action,'' within the meaning of Executive Order 12866, because it raises novel or legal policy issues arising out of the legal mandate established under EEOICPA. The rule is designed to establish objective guidelines, grounded in current science, to support DOL in the adjudication of applicable claims seeking compensation for cancer under EEOICPA. The guidelines will be applied by DOL to calculate a reasonable, scientifically supported determination of the probability that a cancer for which a claimant is seeking compensation was as likely as not caused by radiation doses incurred in the performance of duty by the covered employee. The financial cost to the federal government of applying these guidelines is covered under administrative expenses estimated by DOL under its rule (see FR 28948, May 25, 2001).

The rule carefully explains the manner in which the regulatory action is consistent with the mandate for this action under § 3623(c) of EEOICPA and implements the detailed requirements concerning this action under this section of EEOICPA. The rule does not interfere with State, local, and tribal governments in the exercise of their governmental functions.

The rule is not considered economically significant, as defined in section 3(f)(1) of the Executive Order 12866. This rule has a subordinate role in the adjudication of claims under EEOICPA, serving as one element of an adjudication process administered by DOL under 20 CFR Parts 1 and 30. DOL has determined that its rule fulfills the requirements of Executive Order 12866 and provides estimates of the aggregate cost of benefits and administrative expenses of implementing EEOICPA under its rule (see FR 28948, May 25, 2001).

VI. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, requires each agency to consider the potential impact of its regulations on small entities including small businesses, small governmental units, and small not-for-profit organizations. HHS certifies that this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA. This rule affects only DOL, HHS, and some individuals filing compensation claims under EEOICPA. Therefore, a regulatory flexibility analysis as provided for under RFA is not required.

VII. Paperwork Reduction Act

The Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, requires an agency to invite public comment on and to obtain OMB approval of any regulation that requires ten or more people to report information to the agency or to keep certain records. This rule does not contain any information collection requirements. It provides guidelines only to the U.S. Department of Labor (DOL) for adjudicating compensation claims and thus requires no reporting or record keeping. Information required by DOL to apply these guidelines is being provided by HHS and by individual claimants to DOL under DOL regulations 20 CFR 30. Thus, HHS has determined that the PRA does not apply to this rule.

VIII. Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), the Department will report to Congress promulgation of this rule. The report will state that the Department has concluded that this rule is not a ''major rule'' because it is not likely to result in

[26] ICD–9 is a version of the standard system of classifying diseases that will be used by IREP. The most recent version of this system, ICD–10, will not be used because the cancer risk models have been constructed using ICD–9.

See: The International Classification of Diseases Clinical Modification (9th Revision) Volume I&II. [1991] Department of Health and Human Services Publication No. (PHS) 91–1260, U.S. Government Printing Office, Washington, D.C.

an annual effect on the economy of $100 million or more. However, this rule has a subordinate role in the adjudication of claims under EEOICPA, serving as one element of an adjudication process administered by DOL under 20 CFR Parts 1 and 30. DOL has determined that its rule is a ''major rule'' because it will likely result in an annual effect on the economy of $100 million or more.

IX. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 *et seq.*) directs agencies to assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector, ''other than to the extent that such regulations incorporate requirements specifically set forth in law.'' For purposes of the Unfunded Mandates Reform Act, this rule does not include any Federal mandate that may result in increased annual expenditures in excess of $100 million by State, local or tribal governments in the aggregate, or by the private sector.

X. Executive Order 12988 (Civil Justice)

This rule has been drafted and reviewed in accordance with Executive Order 12988, Civil Justice Reform and will not unduly burden the Federal court system. Probability of causation may be an element in reviews of DOL adverse decisions in the United States District Courts pursuant to the Administrative Procedure Act. However, DOL has attempted to minimize that burden by providing claimants an opportunity to seek administrative review of adverse decisions, including those involving probability of causation. HHS has provided a clear legal standard for DOL to apply regarding probability of causation. This rule has been reviewed carefully to eliminate drafting errors and ambiguities.

XI. Executive Order 13132 (Federalism)

The Department has reviewed this rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have ''federalism implications.'' The rule does not ''have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

XII. Executive Order 13045 (Protection of Children From Environmental, Health Risks and Safety Risks)

In accordance with Executive Order 13045, HHS has evaluated the environmental health and safety effects of this rule on children. HHS has determined that the rule would have no effect on children.

XIII. Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use)

In accordance with Executive Order 13211, HHS has evaluated the effects of this rule on energy supply, distribution or use, and has determined that the rule will not have a significant adverse effect on them.

XIV. Effective Date

The Secretary has determined, pursuant to 5 U.S.C. 553(d)(3), that there is good cause for this rule to be effective immediately to avoid undue hardship on and facilitate payment to eligible claimants.

List of Subjects in 42 CFR Part 81

Cancer, Government Employees, Probability of Causation, Radiation Protection, Radioactive Materials, Workers' Compensation.

Text of the Rule

For the reasons discussed in the preamble, the Department of Health and Human Services is amending 42 CFR to add Part 81 to read as follows:

PART 81—GUIDELINES FOR DETERMINING PROBABILITY OF CAUSATION UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000

Subpart A—Introduction

Subpart B—Definitions

Subpart C—Data Required To Estimate Probability of Causation

Subpart D—Requirements for Risk Models Used To Estimate Probability of Causation

Subpart E—Guidelines To Estimate Probability of Causation

Authority: 42 U.S.C. 7384n(c); E.O. 13179, 65 FR 77487, 3 CFR, 2000 Comp., p. 321.

Subpart A—Introduction

§ 81.0 Background.

The Energy Employees Occupational Illness Compensation Program Act (EEOICPA), 42 U.S.C. 7384–7385 [1994, supp. 2001], provides for the payment of compensation benefits to covered employees and, where applicable, survivors of such employees, of the United States Department of Energy, its predecessor agencies and certain of its contractors and subcontractors. Among the types of illnesses for which compensation may be provided are cancers. There are two categories of covered employees with cancer under EEOICPA for whom compensation may be provided. The regulations that follow under this part apply only to the category of employees described under paragraph (a) of this section.

(a) One category is employees with cancer for whom probability of causation must be estimated or determined, as required under 20 CFR 30.115.

(b) The second category is members of the Special Exposure Cohort seeking compensation for a specified cancer, as defined under EEOICPA. The U.S. Department of Labor (DOL) which has primary authority for implementing EEOICPA, has promulgated regulations at 20 CFR 30.210 et seq. that identify current members of the Special Exposure Cohort and requirements for compensation. Pursuant to section 7384(q) of EEOICPA, the Secretary of HHS is authorized to add additional classes of employees to the Special Exposure Cohort.

§ 81.1 Purpose and Authority.

(a) The purpose of this regulation is to establish guidelines DOL will apply to adjudicate cancer claims for covered employees seeking compensation for cancer, other than as members of the Special Exposure Cohort seeking compensation for a specified cancer. To award a claim, DOL must first determine that it is at least as likely as not that the cancer of the employee was caused by radiation doses incurred by the employee in the performance of

duty. These guidelines provide the procedures DOL must apply and identify the information DOL will use.

(b) Section 7384(n)(b) of EEOICPA requires the President to promulgate these guidelines. Executive Order 13179 assigned responsibility for promulgating these guidelines to the Secretary of HHS.

§ 81.2 Provisions of EEOICPA concerning this part.

EEOICPA imposes several general requirements concerning the development of these guidelines. It requires that the guidelines produce a determination as to whether it is at least as likely as not (a 50% or greater probability) that the cancer of the covered employee was related to radiation doses incurred by the employee in the performance of duty. It requires the guidelines be based on the radiation dose received by the employee, incorporating the methods of dose reconstruction to be established by HHS. It requires determinations be based on the upper 99 percent confidence interval (credibility limit) of the probability of causation in the RadioEpidemiological tables published under section 7(b) of the Orphan Drug Act (42 U.S.C. 241 note), as such tables may be updated. EEOICPA also requires HHS consider the type of cancer, past health-related activities, the risk of developing a radiation-related cancer from workplace exposure, and other relevant factors. Finally, it is important to note EEOICPA does not include a requirement limiting the types of cancers to be considered radiogenic for these guidelines.

Subpart B—Definitions

§ 81.4 Definition of terms used in this part.

(a) Covered employee, for purposes of this part, means an individual who is or was an employee of DOE, a DOE contractor or subcontractor, or an atomic weapons employer, and for whom DOL has requested HHS to perform a dose reconstruction.

(b) *Dose and dose rate effectiveness factor (DDREF)* means a factor applied to a risk model to modify the dose-risk relationship estimated by the model to account for the level of the dose and the rate at which the dose is incurred. As used in IREP, a DDREF value of greater than one implies that chronic or low doses are less carcinogenic per unit of dose than acute or higher doses.

(c) *Dose-response relationship* means a mathematical expression of the way that the risk of a biological effect (for example, cancer) changes with increased exposure to a potential health hazard (for example, ionizing radiation).

(d) *EEOICPA* means the Energy Employees Occupational Illness Compensation Program Act of 2000, 42 U.S.C. §§ 7384–7385 [1994, supp. 2001].

(e) *Equivalent dose* means the absorbed dose in a tissue or organ multiplied by a radiation weighting factor to account for differences in the effectiveness of the radiation in inducing cancer.

(f) *External dose* means the portion of the equivalent dose that is received from radiation sources outside of the body.

(g) *Interactive RadioEpidemiological Program (IREP)* means a computer software program that uses information on the dose-response relationship, and specific factors such as a claimant's radiation exposure, gender, age at diagnosis, and age at exposure to calculate the probability of causation for a given pattern and level of radiation exposure.

(h) *Internal dose* means the portion of the equivalent dose that is received from radioactive materials taken into the body.

(i) *Inverse dose rate effect* means a phenomenon in which the protraction of an exposure to a potential health hazard leads to greater biological effect per unit of dose than the delivery of the same total amount in a single dose. An inverse dose rate effect implies that the dose and dose rate effectiveness factor (DDREF) is less than one for chronic or low doses.

(j) *Linear energy transfer (LET)* means the average amount of energy transferred to surrounding body tissues per unit of distance the radiation travels through body tissues (track length). Low LET radiation is typified by gamma and x rays, which have high penetrating capabilities through various tissues, but transfer a relatively small amount of energy to surrounding tissue per unit of track length. High LET radiation includes alpha particles and neutrons, which have weaker penetrating capability but transfer a larger amount of energy per unit of track length.

(k) *NIOSH* means the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, United States Department of Health and Human Services.

(l) *Non-radiogenic cancer* means a type of cancer that HHS has found not to be caused by radiation, for the purposes of this regulation.

(m) *Primary cancer* means a cancer defined by the original body site at which the cancer was incurred, prior to any spread (metastasis) to other sites in the body.

(n) *Probability of causation* means the probability or likelihood that a cancer was caused by radiation exposure incurred by a covered employee in the performance of duty. In statistical terms, it is the cancer risk attributable to radiation exposure divided by the sum of the baseline cancer risk (the risk to the general population) plus the cancer risk attributable to the radiation exposure.

(o) *RadioEpidemiological Tables* means tables that allow computation of the probability of causation for various cancers associated with a defined exposure to radiation, after accounting for factors such as age at exposure, age at diagnosis, and time since exposure.

(p) *Relative biological effectiveness (RBE)* means a factor applied to a risk model to account for differences between the amount of cancer effect produced by different forms of radiation. For purposes of EEOICPA, the RBE is considered equivalent to the radiation weighting factor.

(q) *Risk model* means a mathematical model used under EEOICPA to estimate a specific probability of causation using information on radiation dose, cancer type, and personal data (e.g., gender, smoking history).

(r) *Secondary site* means a body site to which a primary cancer has spread (metastasized).

(s) *Specified cancer* is a term defined in § 7384(l)(17) of EEOICPA and 20 CFR 30.5(dd) that specifies types of cancer that, pursuant to 20 CFR part 30, may qualify a member of the Special Exposure Cohort for compensation. It includes leukemia (other than chronic lymphocytic leukemia), multiple myeloma, non-Hodgkin's lymphoma, renal cancers, and cancers of the lung (other than carcinoma in situ diagnosed at autopsy), thyroid, male breast, female breast, esophagus, stomach, pharynx, small intestine, pancreas, bile ducts, gall bladder, salivary gland, urinary bladder, brain, colon, ovary, liver (not associated with cirrhosis or hepatitis B), and bone.

(t) *Uncertainty* is a term used in this rule to describe the lack of precision of a given estimate, the extent of which depends upon the amount and quality of the evidence or data available.

(u) *Uncertainty distribution* is a statistical term meaning a range of discrete or continuous values arrayed around a central estimate, where each value is assigned a probability of being correct.

(v) *Upper 99 percent confidence interval* is a term used in EEOICPA to mean credibility limit, the probability of causation estimate determined at the 99th percentile of the range of

uncertainty around the central estimate of probability of causation.

Subpart C—Data Required To Estimate Probability of Causation

§ 81.5 Use of personal and medical information.

Determining probability of causation may require the use of the following personal and medical information provided to DOL by claimants under DOL regulations 20 CFR part 30:

(a) Year of birth

(b) Cancer diagnosis (by ICD–9 code) for primary and secondary cancers

(c) Date of cancer diagnosis

(d) Gender

(e) Race/ethnicity (if the claim is for skin cancer or a secondary cancer for which skin cancer is a likely primary cancer)

(f) Smoking history (if the claim is for lung cancer or a secondary cancer for which lung cancer is a likely primary cancer)

§ 81.6 Use of radiation dose information.

Determining probability of causation will require the use of radiation dose information provided to DOL by the National Institute for Occupational Safety and Health (NIOSH) under HHS regulations 42 CFR part 82. This information will include annual dose estimates for each year in which a dose was incurred, together with uncertainty distributions associated with each dose estimate. Dose estimates will be distinguished by type of radiation (low linear energy transfer (LET), protons, neutrons, alpha, low-energy x-ray) and by dose rate (acute or chronic) for external and internal radiation dose.

Subpart D—Requirements for Risk Models Used To Estimate Probability of Causation

§ 81.10 Use of cancer risk assessment models in NIOSH IREP.

(a) The risk models used to estimate probability of causation for covered employees under EEOICPA will be based on risk models updated from the 1985 NIH Radioepidemiological Tables. These 1985 tables were developed from analyses of cancer mortality risk among the Japanese atomic bomb survivor cohort. The National Cancer Institute (NCI) and Centers for Disease Control and Prevention (CDC) are updating the tables, replacing them with a sophisticated analytic software program. This program, the Interactive RadioEpidemiological Program (IREP)[1], models the dose-response relationship between ionizing radiation and 33 cancers using morbidity data from the same Japanese atomic bomb survivor cohort. In the case of thyroid cancer, radiation risk models are based on a pooled analysis of several international cohorts[1a].

(b) NIOSH will change the risk models in IREP, as needed, to reflect the radiation exposure and disease experiences of employees covered under EEOICPA, which differ from the experiences of the Japanese atomic bomb survivor cohort. Changes will be incorporated in a version of IREP named NIOSH–IREP, specifically designed for adjudication of claims under EEOICPA. Possible changes in IREP risk models include the following:

(1) Addition of risk models to IREP, as needed, for claims under EEOICPA (e.g., malignant melanoma and other skin cancers)

(2) Modification of IREP risk models to incorporate radiation exposures unique to employees covered by EEOICPA (e.g., radon and low energy x rays from employer-required medical screening programs, adjustment of relative biological effectiveness distributions based on neutron energy).

(3) Modification of IREP risk models to incorporate new understanding of radiation-related cancer effects relevant to employees covered by EEOICPA (e.g., incorporation of inverse dose-rate relationship between high LET radiation exposures and cancer; adjustment of the low-dose effect reduction factor for acute exposures).

(4) Modification of IREP risk models to incorporate new understanding of the potential interaction between cancer risk associated with occupational exposures to chemical carcinogens and radiation-related cancer effects.

(5) Modification of IREP risk models to incorporate temporal, race and ethnicity-related differences in the frequency of certain cancers occurring generally among the U.S. population.

(6) Modifications of IREP to facilitate improved evaluation of the uncertainty distribution for the probability of causation for claims based on two or more primary cancers.

§ 81.11 Use of uncertainty analysis in NIOSH–IREP.

(a) EEOICPA requires use of the uncertainty associated with the probability of causation calculation, specifically requiring the use of the upper 99% confidence interval (credibility limit) estimate of the probability of causation estimate. As described in the NCI document,[2] uncertainty from several sources is incorporated into the probability of causation calculation performed by NIOSH–IREP. These sources include uncertainties in estimating: radiation dose incurred by the covered employee; the radiation dose-cancer relationship (statistical uncertainty in the specific cancer risk model); the extrapolation of risk (risk transfer) from the Japanese to the U.S. population; differences in the amount of cancer effect caused by different radiation types (relative biological effectiveness or RBE); the relationship between the rate at which a radiation dose is incurred and the level of cancer risk produced (dose and dose rate effectiveness factor or DDREF); and, the role of non-radiation risk factors (such as smoking history).

(b) NIOSH–IREP will operate according to the same general protocol as IREP for the analysis of uncertainty. It will address the same possible sources of uncertainty affecting probability of causation estimates, and in most cases will apply the same assumptions incorporated in IREP risk models. Different procedures and assumptions will be incorporated into NIOSH–IREP as needed, according to the criteria outlined under § 81.10.

§ 81.12 Procedure to update NIOSH–IREP.

(a) NIOSH may periodically revise NIOSH–IREP to add, modify, or replace cancer risk models, improve the modeling of uncertainty, and improve the functionality and user-interface of NIOSH–IREP.

(b) Revisions to NIOSH–IREP may be recommended by the following sources:

(1) NIOSH,

(2) The Advisory Board on Radiation and Worker Health,

(3) Independent reviews of NIOSH–IREP or elements thereof by scientific organizations (e.g., National Academy of Sciences),

(4) DOL,

(5) Public comment.

(c) NIOSH will submit substantive changes to NIOSH–IREP (changes that would substantially affect estimates of probability of causation calculated using NIOSH–IREP, including the addition of new cancer risk models) to the Advisory Board on Radiation and Worker Health for review. NIOSH will obtain such review and address any recommendations of the review before completing and implementing the change.

[1] NIOSH–IREP is available for public review on the NIOSH homepage at: www.cdc.gov/niosh/ocas/ocasirep/html.

[1a] Ron E, Lubin JH, Shore RE, et al. ''Thyroid cancer after exposure to external radiation: a pooled analysis of seven studies.'' Radiat. Res. 141:259–277, 1995.

[2] Draft Report of the NCI–CDC Working Group to Revise the 1985 NIH Radioepidemiological Tables, May 31, 2000, p. 17–18, p. 22–23.

(d) NIOSH will inform the public of proposed changes provided to the Advisory Board for review. HHS will provide instructions for obtaining relevant materials and providing public comment in the notice announcing the Advisory Board meeting, published in the **Federal Register**.

(e) NIOSH will publish periodically a notice in the **Federal Register** informing the public of proposed substantive changes to NIOSH–IREP currently under development, the status of the proposed changes, and the expected completion dates.

(f) NIOSH will notify DOL and publish a notice in the **Federal Register** notifying the public of the completion and implementation of substantive changes to NIOSH–IREP. In the notice, NIOSH will explain the effect of the change on estimates of probability of causation and will summarize and address relevant comments received by NIOSH.

(g) NIOSH may take into account other factors and employ other procedures than those specified in this section, if circumstances arise that require NIOSH to implement a change more immediately than the procedures in this section allow.

Subpart E—Guidelines To Estimate Probability of Causation

§ 81.20 Required use of NIOSH–IREP.

(a) NIOSH–IREP is an interactive software program for estimating probability of causation for covered employees seeking compensation for cancer under EEOICPA, other than as members of the Special Exposure Cohort seeking compensation for a specified cancer.

(b) DOL is required to use NIOSH–IREP to estimate probability of causation for all cancers, as identified under §§ 81.21 and 81.23.

§ 81.21 Cancers requiring the use of NIOSH–IREP.

(a) DOL will calculate probability of causation for all cancers, except chronic lymphocytic leukemia as provided under § 81.30, using NIOSH–IREP.

(b) Carcinoma in situ (ICD–9 codes 230–234), neoplasms of uncertain behavior (ICD–9 codes 235–238), and neoplasms of unspecified nature (ICD–9 code 239) are assumed to be malignant, for purposes of estimating probability of causation.

(c) All secondary and unspecified cancers of the lymph node (ICD–9 code 196) shall be considered secondary cancers (cancers resulting from metastasis of cancer from a primary site). For claims identifying cancers of the lymph node, Table 1 in § 81.23 provides guidance for assigning a primary site and calculating probability of causation using NIOSH–IREP.

§ 81.22 General guidelines for use of NIOSH–IREP.

DOL will use procedures specified in the NIOSH–IREP Operating Guide to calculate probability of causation estimates under EEOICPA. The guide provides current, step-by-step instructions for the operation of IREP. The procedures include entering personal, diagnostic, and exposure data; setting/confirming appropriate values for variables used in calculations; conducting the calculation; and, obtaining, evaluating, and reporting results.

§ 81.23 Guidelines for cancers for which primary site is unknown.

(a) In claims for which the primary cancer site cannot be determined, but a site of metastasis is known, DOL will calculate probability of causation estimates for various likely primary sites. Table 1, below, indicates the primary cancer site(s) DOL will use in NIOSH–IREP when the primary cancer site is unknown.

Table 1

Primary cancers (ICD–9 codes [3]) for which probability of causation is to be calculated, if only a secondary cancer site is known. ''M'' indicates cancer site should be used for males only, and ''F'' indicates the cancer site should be used for females only. A glossary of cancer descriptions for each ICD–9 code is provided in Appendix A to this part.

Secondary cancer (ICD–9 code)	ICD–9 code of likely primary cancers
Lymph nodes of head, face and neck (196.0)	141, 142 (M), 146 (M), 149 (F), 161 (M), 162, 172, 173, 174 (F), 193 (F).
Intrathoracic lymph nodes (196.1)	150 (M), 162, 174 (F).
Intra-abdominal lymph nodes (196.2)	150 (M), 151 (M), 153, 157 (F), 162, 174 (F), 180 (F), 185 (M), 189, 202 (F).
Lymph nodes of axilla and upper limb (196.3)	162, 172, 174 (F).
Inguinal and lower limb lymph nodes (196.5)	154 (M), 162, 172, 173 (F), 187 (M).
Intrapelvic lymph nodes (196.6)	153 (M), 154 (F), 162 (M), 180 (F), 182 (F), 185 (M), 188.
Lymph nodes of multiple sites (196.8)	150 (M), 151 (M), 153 (M), 162, 174 (F).
Lymph nodes, site unspecified (196.9)	150 (M), 151, 153, 162, 172, 174 (F), 185 (M).
Lung (197.0)	153, 162, 172 (M), 174 (F), 185 (M), 188 (M), 189.
Mediastinum (197.1)	150 (M), 162, 174 (F).
Pleura (197.2)	150 (M), 153 (M), 162, 174 (F), 183 (F), 185 (M), 189 (M).
Other respiratory organs (197.3)	150, 153 (M), 161, 162, 173 (M), 174 (F), 185 (M), 193 (F).
Small intestine, including duodenum (197.4)	152, 153, 157, 162, 171, 172 (M), 174 (F), 183 (F), 189 (M).
Large intestine and rectum (197.5)	153, 154, 162, 174 (F), 183 (F), 185 (M).
Retroperitoneum and peritoneum (197.6)	151, 153, 154 (M), 157, 162 (M), 171, 174 (F), 182 (F), 183 (F).
Liver, specified as secondary (197.7)	151 (M), 153, 154 (M), 157, 162, 174 (F).
Other digestive organs (197.8)	150 (M), 151, 153, 157, 162, 174 (F), 185 (M).
Kidney (198.0)	153, 162, 174 (F), 180 (F), 185 (M), 188, 189, 202 (F).
Other urinary organs (198.1)	153, 174 (F), 180 (F), 183 (F), 185 (M), 188, 189 (F).
Skin (198.2)	153, 162, 171 (M), 172, 173 (M), 174 (F), 189 (M).
Brain and spinal cord (198.3)	162, 172 (M), 174 (F).
Other parts of nervous system (198.4)	162, 172 (M), 174 (F), 185 (M), 202.
Bone and bone marrow (198.5)	162, 174 (F), 185 (M).
Ovary (198.6)	153 (F), 174 (F), 183 (F).
Suprarenal gland (198.7)	153 (F), 162, 174 (F).
Other specified sites (198.8)	153, 162, 172 (M), 174 (F), 183 (F), 185 (M), 188 (M).

[3] The International Classification of Diseases Clinical Modification (9th Revision) Volume I&II. [1991] Department of Health and Human Services Publication No. (PHS) 91–1260, U.S. Government Printing Office, Washington D.C.

(b) DOL will select the site producing the highest estimate for probability of causation to adjudicate the claim.

§ 81.24 Guidelines for leukemia.

(a) For claims involving leukemia, DOL will calculate one or more probability of causation estimates from up to three of the four alternate leukemia risk models included in NIOSH–IREP, as specified in the NIOSH–IREP Operating Guide. These include: ''Leukemia, all types except CLL'' (IDC–9 codes: 204–208, except 204.1), ''acute lymphocytic leukemia'' (ICD–9 code: 204.0), and ''acute myelogenous leukemia'' (ICD–9 code: 205.0).

(b) For leukemia claims in which DOL calculates multiple probability of causation estimates, as specified in the NIOSH–IREP Operating Guide, the probability of causation estimate DOL assigns to the claim will be based on the leukemia risk model producing the highest estimate for probability of causation.

§ 81.25 Guidelines for claims including two or more primary cancers.

For claims including two or more primary cancers, DOL will use NIOSH–IREP to calculate the estimated probability of causation for each cancer individually. Then DOL will perform the following calculation using the probability of causation estimates produced by NIOSH–IREP:

EQUATION 1

Calculate: $1-[\{1\times PC_1\}\times\{1-PC_2\}\times \ldots\times \{1-PC_n\}] = PC_{total}$,

where PC_1 is the probability of causation for one of the primary cancers identified in the claim, PC_2 is the probability of causation for a second primary cancer identified in the claim, and PC_n is the probability of causation for the nth primary cancer identified in the claim. PC_{total} is the probability that at least one of the primary cancers (cancers 1 through ''n'') was caused by the radiation dose estimated for the claim when Equation 1 is evaluated based on the joint distribution of $PC_1, \ldots, PC_n$.[4] DOL will use the probability of causation value calculated for PC_{total} to adjudicate the claim.

§ 81.30 Non-radiogenic cancers

The following cancers are considered non-radiogenic for the purposes of EEOICPA and this part. DOL will assign a probability of causation of zero to the following cancers:

(a) Chronic lymphocytic leukemia (ICD–9 code: 204.1)

(b) [Reserved]

[4] Evaluating Equation 1 based on the individual upper 99th percentiles of $PC_1, \ldots, PC_n$ approximates the upper 99th percentile of PC_{total} whenever $PC_1, \ldots, PC_n$ are highly related, e.g., when a common dose-reconstruction is the only non-negligible source of uncertainty in the individual PC_i's. However, this approximation can overestimate it if other sources of uncertainty contribute independently to the $PC_1, \ldots, PC_n$, whereas treating the joint distribution as fully independent could substantially underestimate the upper 99th percentile of PC_{total} whenever the individual PC_i's are positively correlated.

Appendix A to Part 81—Glossary of ICD–9 Codes and Their Cancer Descriptions [1]

ICD–9 code	Cancer description
140	Malignant neoplasm of lip.
141	Malignant neoplasm of tongue.
142	Malignant neoplasm of major salivary glands.
143	Malignant neoplasm of gum.
144	Malignant neoplasm of floor of mouth.
145	Malignant neoplasm of other and unspecified parts of mouth.
146	Malignant neoplasm of oropharynx.
147	Malignant neoplasm of nasopharynx.
148	Malignant neoplasm of hypopharynx.
149	Malignant neoplasm of other and ill-defined sites within the lip, oral cavity, and pharynx.
150	Malignant neoplasm of esophagus.
151	Malignant neoplasm of stomach.
152	Malignant neoplasm of small intestine, including duodenum.
153	Malignant neoplasm of colon.
154	Malignant neoplasm of rectum, rectosigmoid junction, and anus.
155	Malignant neoplasm of liver and intrahepatic bile ducts.
156	Malignant neoplasm of gall bladder and extrahepatic bile ducts.
157	Malignant neoplasm of pancreas.
158	Malignant neoplasm of retroperitoneum and peritoneum.
159	Malignant neoplasm of other and ill-defined sites within the digestive organs and peritoneum.
160	Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses.
161	Malignant neoplasm of larynx.
162	Malignant neoplasm of trachea, bronchus and lung.
163	Malignant neoplasm of pleura.
164	Malignant neoplasm of thymus, heart, and mediastinum.
165	Malignant neoplasm of other and ill-defined sites within the respiratory system and intrathoracic organs.
170	Malignant neoplasm of bone and articular cartilage.
171	Malignant neoplasm of connective and other soft tissue.
172	Malignant melanoma of skin.
173	Other malignant neoplasms of skin.
174	Malignant neoplasm of female breast.
175	Malignant neoplasm of male breast.
179	Malignant neoplasm of uterus, part unspecified.
180	Malignant neoplasm of cervix uteri.
181	Malignant neoplasm of placenta.
182	Malignant neoplasm of body of uterus.
183	Malignant neoplasm of ovary and other uterine adnexa.
184	Malignant neoplasm of other and unspecified female genital organs.
185	Malignant neoplasm of prostate.
186	Malignant neoplasm of testis.

APPENDIX A TO PART 81—GLOSSARY OF ICD–9 CODES AND THEIR CANCER DESCRIPTIONS [1]—Continued

ICD–9 code	Cancer description
187	Malignant neoplasm of penis and other male genital organs.
188	Malignant neoplasm of urinary bladder.
189	Malignant neoplasm of kidney and other unspecified urinary organs.
190	Malignant neoplasm of eye.
191	Malignant neoplasm of brain.
192	Malignant neoplasm of other and unspecified parts of nervous system.
193	Malignant neoplasm of thyroid gland.
194	Malignant neoplasm of other endocrine glands and related structures.
195	Malignant neoplasm of other and ill-defined sites.
196	Secondary and unspecified malignant neoplasm of the lymph nodes.
197	Secondary malignant neoplasm of the respiratory and digestive organs.
198	Secondary malignant neoplasm of other tissue and organs.
199	Malignant neoplasm without specification of site.
200	Lymphosarcoma and reticulosarcoma.
201	Hodgkin's disease.
202	Other malignant neoplasms of lymphoid and histiocytic tissue.
203	Multiple myeloma and other immunoproliferative neoplasms.
204	Lymphoid leukemia
205	Myeloid leukemia.
206	Monocytic leukemia.
207	Other specified leukemia.
208	Leukemia of unspecified cell type.

[1] The International Classification of Diseases Clinical Modification (9th Revision) Volume I&II. [1991] Department of Health and Human Services Publication No. (PHS) 91–1260, U.S. Government Printing Office, Washington, D.C.

Dated: April 10, 2002.

Tommy G. Thompson,

Secretary, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 82

RIN 0920–ZA00

Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Final Rule

AGENCY: Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: This rule implements select provisions of the Energy Employees Occupational Illness Compensation Program Act of 2000 (''EEOICPA'' or ''Act''). The Act requires the promulgation of methods, in the form of regulations, for estimating the dose levels of ionizing radiation incurred by workers in the performance of duty for nuclear weapons production programs of the Department of Energy and its predecessor agencies. These ''dose reconstruction'' methods will be applied by the National Institute for Occupational Safety and Health, which is responsible for producing the radiation dose estimates that the U.S. Department of Labor will use in adjudicating certain cancer claims under the Act.

DATES: *Effective Date:* This final rule is effective May 2, 2002.

Compliance Dates: Affected parties are required to comply with the information collection requirements in § 82.10 May 2, 2002.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS-R45, Cincinnati, OH 45226, Telephone 513–841–4498 (this is not a toll-free number). Information requests may also be submitted by e-mail to *OCAS@CDC.GOV*.

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Authority

The Energy Employees Occupational Illness Compensation Program Act of 2000 (''EEOICPA''), 42 U.S.C. 7384–7385 [1994, supp. 2001], established a compensation program to provide a lump sum payment of $150,000 and medical benefits as compensation to covered employees suffering from designated illnesses (i.e. cancer resulting from radiation exposure, chronic beryllium disease, or silicosis) incurred as a result of their exposures while in the performance of duty for the Department of Energy (''DOE'') and certain of its vendors, contractors, and subcontractors. This law also provided for payment of compensation to certain survivors of covered employees.

EEOICPA instructed the President to designate one or more federal agencies to carry out the compensation program. Pursuant to this statutory provision, the President issued Executive Order 13179, titled Providing Compensation to America's Nuclear Weapons Workers, which assigned primary responsibility for administering the compensation program to the Department of Labor (''DOL''). 65 FR 77487 (Dec. 7, 2000). DOL published an interim final rule governing DOL's administration of EEOICPA on May 25, 2001 (20 CFR parts 1 and 30).

The executive order directed the Department of Health and Human Services (''HHS'') to perform several technical and policymaking roles in support of the DOL program:

(1) HHS is to develop methods to estimate radiation doses (''dose reconstruction'') for certain individuals with cancer applying for benefits under the DOL program. These methods are the subject of this rule. HHS is also to apply these methods to conduct the program of dose reconstructions required by EEOICPA. This program is delegated to the National Institute for Occupational Safety and Health (''NIOSH''), an institute of the Centers for Disease Control and Prevention.

(2) HHS is also to develop guidelines to be used by DOL to assess the likelihood that an employee with cancer developed that cancer as a result of exposure to radiation in performing his or her duties at a DOE facility or atomic

weapons facility. These guidelines were published as a notice of proposed rulemaking under 42 CFR Part 81 on October 5, 2001, and are being published as a final rule simultaneously with this rule in this issue of the **Federal Register**.

(3) HHS is to staff the Advisory Board on Radiation and Worker Health and provide it with administrative and other necessary support services. The Board, a federal advisory committee, was appointed by the President in November 2001. It first convened on January 22, 2002, and is advising HHS in implementing its roles under EEOICPA described here.

(4) Finally, HHS is to develop and apply procedures for considering petitions by classes of employees at DOE or Atomic Weapons Employer facilities seeking to be added to the Special Exposure Cohort established under EEOICPA. Employees included in the Special Exposure Cohort who have a specified cancer and meet other conditions, as defined by EEOICPA and DOL regulations (20 CFR 30), qualify for compensation under EEOICPA. Proposed HHS procedures for considering Special Exposure Cohort petitions will be published soon in the **Federal Register**. HHS will obtain public comment and a review by the Advisory Board on Radiation and Worker Health before these procedures are made final and implemented.

As provided for under 42 U.S.C. 7384p, HHS is implementing its responsibilities with the assistance of NIOSH.

B. What Legal Requirements Are Specified by EEOICPA for Dose Reconstruction?

EEOICPA requires that HHS establish, by regulation, methods for arriving at reasonable estimates of the radiation doses incurred by covered employees in connection with claims seeking compensation for cancer, other than as members of the Special Exposure Cohort. 42 U.S.C. 7384n(d). These methods will be applied to estimate radiation doses for the following covered employees: (1) An employee who was not monitored for exposure to radiation at a DOE or Atomic Weapons Employer facility; (2) an employee who was monitored inadequately for exposure to radiation at such a facility; or (3) an employee whose records of exposure to radiation at such facility are missing or incomplete.

EEOICPA requires the Advisory Board on Radiation and Worker Health to independently review the methods established by this rule and to verify a reasonable sample of dose reconstructions established under these methods. The Advisory Board is a federal advisory committee established by the statute and appointed by the President which is advising HHS on its major responsibilities under EEOICPA.

EEOICPA requires that DOE provide HHS with relevant information on worker radiation exposures necessary for dose reconstructions and requires DOE to inform covered employees with cancer of the results of their dose reconstructions. 42 U.S.C. 7384n(e) and 7384q(c). NIOSH, which will be conducting the dose reconstructions, will inform covered employees and DOE of the results of these dose reconstructions.

Subject to provisions of the Privacy Act (5 U.S.C. 552(a)), HHS will also make available to researchers and the general public information on the assumptions, methodology, and data used in estimating radiation doses. 42 U.S.C. 7384n(e)(2).

Finally, HHS notes that EEOICPA does not authorize the establishment of new radiation protection standards through the promulgation of these methods, and these methods do not constitute such new standards.

C. What Is the Purpose of Dose Reconstruction?

Dose reconstructions are used to estimate the radiation doses to which individual workers or groups of workers have been exposed, particularly when radiation monitoring is unavailable, incomplete, or of poor quality. Originally dose reconstructions were conducted for research on the health effects of exposure to radiation. In recent decades, dose reconstruction has become an integral component of radiation illness compensation programs in the United States and internationally.

D. How Are Radiation Doses Reconstructed?

The procedures and level of effort involved in dose reconstructions depend in part on the quantity and quality of available dose monitoring information, the conditions under which radiation exposure arose, and the forms of radiation to which the individual was exposed. If individuals for whom dose estimates are needed were monitored using present day technology and received only external radiation doses, dose reconstruction could be very simple. It might only require summing the radiation doses recorded from radiation badges and adding estimated potential ''missed'' doses resulting from the limits of detection of monitoring badges.

Dose reconstruction can require extensive research and analysis. Such work is required if radiation doses were not monitored or there is uncertainty about the monitoring methods involved; if there was potential for internal doses through the ingestion, inhalation or absorption of radioactive materials; or if the processes and circumstances involved in the radiation exposures were complex. For the most complex dose reconstructions, research and analyses may include determining or assuming specific characteristics of the monitoring procedures; identifying events or processes that were unmonitored; identifying the types and quantities of radioactive materials involved; evaluating production processes and safety procedures employed; identifying the locations and activities of exposed persons; identifying comparable exposure circumstances for which data is available to make assumptions; and conducting a variety of complex analyses to interpret the data compiled or estimated.

E. How Is Dose Reconstruction Conducted in a Compensation Program?

An additional, critical factor affecting how doses are reconstructed is the amount of time available. For health research studies dose reconstructions may take from months to years to complete. In compensation programs, however, a balance must be struck between efficiency and precision. Section 7384d of EEOICPA specifically states that one of the purposes of the compensation program is to provide for ''timely'' compensation. As applied under EEOICPA, dose reconstruction must rely on information that can be developed on a timely basis and on carefully developed assumptions.

When conducting dose reconstruction for a compensation program, our primary concern will be to ensure the assumptions used to estimate doses are fair, consistent, and well grounded in the best available science. To address fairness, the Defense Threat Reduction Agency (''DTRA''), which conducts dose reconstructions for veterans and Department of Defense civilian personnel who participated in U.S. atmospheric nuclear testing and in the occupation forces of Hiroshima and Nagasaki, applies certain assumptions that err reasonably on the side of overestimating exposures (*see* 32 CFR part 218). These assumptions substitute for more detailed information that would be time-consuming and costly to develop. HHS will take an approach similar to that of DTRA by using reasonable, fair, and scientifically based

assumptions as substitutes for additional research and analysis to achieve an efficient dose reconstruction process.

F. How Will Dose Reconstruction Methods Under EEOICPA Differ From Dose Reconstruction for Veterans?

The major differences for the HHS methods for dose reconstructions arise from characteristics that distinguish the radiation exposure experiences of nuclear weapons production workers from those of veterans. Whereas veterans were primarily exposed to external sources of radiation over brief periods in acute doses, employees covered by EEOICPA frequently may have received both acute and chronic exposures to internal and external radiation over periods as long as three to four decades. Further, nuclear weapons production employees experienced more diverse exposures and circumstances of exposure, on an individual basis and as a group than did veterans. As a result, many HHS dose reconstructions will be more complex than those conducted by DTRA, making it necessary that HHS place a high premium on any efficiencies that can be achieved.

Addressing the need for efficiency, HHS is establishing a dose reconstruction process that limits the work performed in cases where it is evident the outcome of the compensation claim will be unaffected. HHS will rely on less detailed or precise estimates for claims for which compensation would clearly be due based on the more limited dose reconstruction, and for claims for which additional work clearly would not result in compensation. In the former case, if it is evident from limited dose reconstruction that the estimated cumulative dose is sufficient to qualify the claimant for compensation, no additional work will be performed. In the latter case, limited dose reconstructions will be conducted only for claims for which it is evident that further research and dose reconstruction will not produce a compensable level of radiation dose, because the use of worst-case assumptions does not produce a compensable level of radiation dose. In these latter cases, the decisive factors that result in NIOSH deciding to limit the dose reconstruction process will be clearly explained in the draft of the dose reconstruction results reported to the claimant under § 82.25, and in the dose reconstruction results reported to the claimant under § 82.26.

A second important aspect of the HHS dose reconstruction process is that it will involve interaction with the covered employee or survivor. NIOSH will use information provided by the claimant to evaluate the completeness and adequacy of dose information available, to locate additional exposure or dose-related information, and to estimate unmonitored doses.

G. How Will HHS Incorporate Scientific Methods Established by the Radiation Safety Scientific Community in Internal Dose Estimation Under EEOICPA?

The methods for calculating internal dose under this rule use current models published by the International Commission on Radiological Protection (ICRP). Specifically, at this time NIOSH will use the new ICRP respiratory tract model for assessing doses due to inhalation of radioactive particles. [1] In addition, NIOSH will use the new biokinetic models for the radionuclides contained in publications 56,[2] 67 [3] and 69 [4] in place of those described in previous ICRP publications. These models currently provide the most widely accepted methods for mathematically describing the uptake, transport and retention of radionuclides in the body.

H. What Elements Underlying the Dose Reconstruction Process Are Expected To Change With Scientific Progress?

ICRP periodically updates the models used to evaluate internal doses, based on new research on the metabolic properties of radioactive materials (radionuclides). These ICRP updates reflect the current state of scientific knowledge on the uptake, transport, and retention of radionuclides in the human body.

In addition, technological advances in the areas of retrospective detection of radiation exposure or radiation exposure and dose biomarkers (detectable changes in human tissues and/or physiologic processes resulting from radiation exposure) may make it possible to add new analyses to the dose reconstruction process in the future.

As described in §§ 82.30–82.33 of the rule, NIOSH will address the need to update the scientific elements underlying dose reconstructions in a process that involves review by the Advisory Board on Radiation and Worker Health and permits and facilitates input from the public.

II. Summary of Public Comments

On October 5, 2001, HHS promulgated an interim final rule issuing methods for conducting dose reconstructions under EEOICPA (42 CFR part 82; see 66 FR 50978). Public comments were solicited initially from October 5, 2001 to November 5, 2001. The public comment period was reopened subsequently from January 17, 2002, to January 23, 2002; from January 17, 2002, to February 6, 2002, for comments from the Advisory Board on Radiation and Worker Health; and from February 14, 2002, to March 1, 2002.

HHS received comments from 13 organizations and 23 individuals. Organizations commenting included several labor unions representing DOE workers, a community based organization, an administrative office of the University of California, several DOE contractors, and several federal agencies. A summary of these comments and HHS responses is provided below. These are organized by general topical area.

A. Purpose of the Rule

HHS received various comments regarding the purpose of the rule.

Several comments concerned the general issue of whether or not the rule includes sufficient technical detail. Several commenters recommended HHS specify the detailed assumptions and technical methods that might be used in a dose reconstruction. Another commenter supported retaining the general level of detail included in the interim rule. One commenter recommended the comment period on the rule remain open until the public has had opportunity to review the dose reconstruction technical procedures discussed in the interim final rule.

The approach of this rule is to establish the principles, general procedures, and general criteria by which the NIOSH dose reconstruction program will operate. Very specific details about the technical procedures that may be involved in a dose reconstruction are established in NIOSH implementation guides and will be available for public review as discussed in this rule. These detailed technical procedures were presented in draft form

[1] International Commission on Radiological Protection (ICRP). 1994. Human Respiratory Model for Radiological Protection. ICRP Publicatiaon 66, Annals of the ICRP 24(1–4). Elsevier Scientific Ltd., Oxford.

[2] International Commission on Radological Protection (ICRP). 1989. Age Dependent Doses to Members of the Public from Intakes of Radionuclides: Part 1. ICRP Publication 56, Annals of the ICRP 20(2). Pergamon Press, Oxford.

[3] International Commission on Radiological Protection (ICRP). 1993. Age Dependent Doses to Members of the Public from Intakes of Radionuclides: Part 2 ICRP Publication 67, Annals of the ICRP 23(⅔). Pergamon Press, Oxford.

[4] International Commission on Radiological Protection (ICRP). 1995. Age Dependent Doses to Members of the Public from Intakes of Radionuclides: Part 3: Ingestion Dose Coefficients. ICRP Publication 69, Annals of the ICRP 25(1). Elsevier Scientific Ltd., Oxford.

to the Advisory Board on Radiation and Worker Health on January 24 and February 13, 2002. Further detail will be established as standard operating procedures as procedural issues arise in performing dose reconstructions.

This approach to regulation is necessary because the level of possible detail is far too great to encompass in a reasonably comprehensible regulation. Many specific circumstances that might arise in dose reconstructions either cannot be anticipated with reasonable certainty or cannot be identified and addressed without causing a great delay in the initiation of the dose reconstruction program, seriously harming claimants already awaiting decisions on compensation. This approach is appropriate because the public is provided a clear explanation of the general approach of the dose reconstruction procedures and the principles and criteria that will guide implementation of these procedures. And the public will have the opportunity to review the procedures set forth in the NIOSH implementation guides as they are developed and at any time thereafter.

Several commenters requested HHS define what constitutes a ''reasonable estimate'' of the radiation doses incurred by an employee. EEOICPA requires the dose reconstruction program to arrive at ''reasonable estimates'' of these doses (42 U.S.C. 7384n(d)).

HHS interprets this term to mean estimates calculated using a substantial basis of fact and the application of science-based, logical assumptions to supplement or interpret the factual basis. As discussed in the interim final rule, assumptions applied by NIOSH will give the benefit of the doubt to claimants in cases of scientific or factual uncertainty or unknowns.

One commenter noted that the single purpose of dose reconstructions under EEOICPA is to support compensation decisions by DOL and recommended HHS clarify the limitations of the dose reconstruction findings arising from this circumstance.

As discussed above and in the interim final rule, NIOSH is applying methods designed to support compensation decisions by DOL that are fair and as timely as possible. As a consequence, many of the NIOSH dose reconstruction results are likely to differ substantially from those that would be produced under a scientific research protocol, when the principal object is to produce maximally complete and precise estimates. Under the methods promulgated in this rule and consistent with the intent of Congress, NIOSH will give the benefit of the doubt to claimants when there is uncertainty or unknowns concerning radiation exposures. This will tend to overestimate radiation doses for employees, except for those employees for whom immediately available records reveal doses sufficiently high to produce a compensable level of probability of causation. For these employees whose dose levels can be immediately determined to be compensable, NIOSH will tend to underestimate their total cumulative doses by abbreviating the dose reconstruction process. Further dose reconstruction for these latter claimants, however, would be unnecessary and harmful. It would prolong the adjudication process without benefit to the claimant (since the abbreviated dose reconstruction has already estimated a compensable level of radiation dose), and at the cost of unnecessarily delaying dose reconstructions for other claimants.

For the reasons discussed above, a dose reconstruction conducted by NIOSH will not always produce complete or best estimates of the actual doses received by an individual. HHS does not believe that the dose reconstruction results should be used for any purpose other than the probability of causation calculations required under EEOICPA.

B. Claimant Involvement

HHS received various comments concerning the involvement of claimants in the dose reconstruction process and other related claims processes.

Several commenters recommended that the claimant not be burdened with collecting the records needed for the dose reconstruction. Another commenter recommended that the claimant have an opportunity to contribute information for the dose reconstruction.

The former comments appear to stem from a misunderstanding of the role of claimant interviews in the dose reconstruction process. As outlined in the interim final rule and this final rule, DOE will provide the records needed for dose reconstruction directly to NIOSH in response to requests by NIOSH. The claimant is generally not burdened with collecting dosimetry and related data.

The purpose of the claimant interview is to capture any information or records available to the claimant that might not be initially identified by or available from DOE or AWEs; as well as information that would help NIOSH interpret DOE records, such as information on radiation dosimetry badge practices or placement of radiation area monitors or particulars of work practices; or information that might be missing from DOE records, such as radiation monitoring results, information connecting an employee with a radiation contamination incident, or medical records indicating the employee received medical treatment resulting from radiation exposure.

The contribution of information from claimants (and also coworkers when the claimant is a survivor of a covered employee) is entirely voluntary. It is intended to improve, when possible and necessary, the dose reconstruction record that can be established using DOE records and the records and results of research conducted at DOE or AWE facilities or research evaluating the health of DOE or AWE employees.

One commenter requested clarification of the interview options in cases when the claimant is a survivor.

As noted above, when the claimant is a survivor, NIOSH will interview the claimant and will also attempt to interview one or more co-workers of the employee. HHS recognizes that survivors frequently will not know much, if anything, about working conditions, work procedures, or dosimetry practices at DOE facilities, even when the survivor is the spouse of an employee. Interviews with co-workers are intended to supplement information available from the survivor.

One commenter recommended that when the federal compensation program of EEOICPA, administered by DOL, denies a cancer claim and the employee involved in the claim had a combination of radiation and chemical exposures, the federal government should itself submit a compensation claim on behalf of the claimant to the workers' compensation program in the state with jurisdiction. The commenter's intent is to reduce the burden on the claimant who has already filed for compensation once, under the federal EEOICPA compensation program.

The federal government does not have legal authority to file compensation claims with state workers' compensation programs on behalf of nuclear weapons employees. On the other hand, the federal government has established a program to assist DOE contractor employees in obtaining compensation from state workers' compensation programs for any illnesses that may have been caused by toxic exposures at DOE facilities, including cancers potentially caused by a combination of radiation and chemical exposures or either of these types of exposures individually. The DOE Office of Worker Advocacy is authorized to conduct this program under Part D of

EEOICPA. The program includes the establishment of physicians panels, appointed by HHS, to evaluate the work-relatedness of such illnesses and the establishment of agreements between DOE and individual states to facilitate the consideration of these compensation claims.

The public should note, however, that claimants under the federal EEOICPA compensation program are eligible to seek compensation from state workers' compensation programs regardless of the outcome of their federal claim. A decision by DOL to compensate a claimant under the federal program provides no guarantee, in and of itself, that a state compensation program will also compensate the claimant. These programs are legally and administratively independent, apart from any agreements that might be entered into by DOE and individual state workers' compensation programs.

One commenter recommended NIOSH re-analyze completed dose reconstructions without a request by the claimant when NIOSH obtains new data or information that could substantially change the findings of the completed dose reconstruction. This comment is relevant to two foreseeable circumstances: (1) When NIOSH discovers records or information on previously unidentified or possibly underestimated radiation exposures at DOE or AWE facilities; and (2) when NIOSH modifies the scientific elements underlying dose reconstructions, such as the biokinetic models used to estimate internal radiation doses.

HHS agrees with the comment and has added provisions under § 82.27 of this rule to authorize NIOSH to review completed dose reconstructions on its own initiative, upon obtaining new information or changing scientific elements underlying dose reconstructions. HHS has targeted the added provisions to circumstances in which use of the new information or scientific element could increase the levels of radiation doses previously estimated, since the purpose of these provisions is to provide new information to DOL on claims that were denied based on outdated information.

One commenter recommended that the federal government provide claimants with resources to obtain independent reviews of NIOSH dose reconstructions.

HHS will not fund claimants to obtain independent reviews of dose reconstructions. EEOICPA already provides for an independent review of the NIOSH dose reconstruction program by the Advisory Board on Radiation and Worker Health, funded by HHS. This review will be periodic and include a sample of completed dose reconstructions. NIOSH will also establish several levels of quality assurance procedures integral to the dose reconstruction process. The proposal for HHS to fund further independent reviews is largely duplicative of these current efforts and hence, unlikely to benefit claimants or further improve the NIOSH dose reconstruction program.

C. Basics of Dose Reconstruction

HHS received several comments addressing provisions on the basic approach of dose reconstructions described under § 82.2 of the interim final rule.

Several commenters were uncertain how to interpret the ''hierarchy of methods'' described under this section. The commenters were concerned that NIOSH might exclusively analyze monitoring data on individual workers, when such data are available, without taking under consideration other relevant data, such as area monitoring, information on monitoring practices and technology, or information on unrecorded exposures or missing records.

It is first important to note, this section provides only a general outline on the basic approach of dose reconstructions. It is intended to introduce readers to the elementary concepts of dose reconstruction, which is why it is included in the ''Introduction'' subpart of the rule. Section 82.10 and following sections provide detail on the specific procedures NIOSH must follow in conducting a dose reconstruction.

Second, the hierarchical use of dose reconstruction methods discussed in this section implicitly requires the consideration of data from various sources. The provision of this section which gives highest priority to individual monitoring data begins with the conditional statement: ''If found to be complete and adequate, individual worker monitoring data...are given the highest priority in assessing exposure.'' To evaluate whether individual monitoring data are complete and adequate, NIOSH may have to examine and consider the full scope of sources and types of data available and relevant, as described under the detailed procedural sections of the rule beginning with § 82.10. NIOSH will have to examine other sources and types of data to properly interpret primary data, even when they are complete and adequate, as explained in § 82.2.

One commenter recommended HHS explain in detail in this section how NIOSH would evaluate data adequacy.

As discussed above, this section is introductory and general. Section 82.15 of the rule explains in some detail how NIOSH will evaluate the completeness and adequacy of individual monitoring data. NIOSH has prepared implementation guides that provide additional detail, and will be preparing standard operating procedures as needed to address issues that arise as NIOSH conducts dose reconstructions. The implementation guides will be available to the public from the NIOSH addresses provided above and the standard operating procedures will also be made available as they are established.

Several commenters requested HHS clarify the meaning of the expression used in this section: ''reasonable and scientific assumptions.'' This section explains that dose reconstructions use such assumptions in establishing default values to supplement existing data on workplace radiation exposures. This expression is intended to mean assumptions that follow logically from scientific experience and a factual basis. For example, dosimetrists assume that a process operating at different times or in different places but involving the same source term used under comparable conditions, controls, and practices will produce comparable radiation exposure levels and characteristics.

One commenter suggested a substantive edit to the last sentence under § 82.2(a), which provides an example of a situation in which a dose reconstruction would employ a worst case assumption to substitute for lack of information on the solubility of an inhaled material. The commenter recommended that HHS clarify in this example that the worst case assumption would be reasonable. HHS has clarified this sentence accordingly. The sentence now reads: ''For example, if the solubility classification of an inhaled material cannot be determined, the dose reconstruction would use the classification that results in the largest dose to the organ or tissue relevant to the cancer and that is possible given existing knowledge of the material and process.''

D. Who Receives Dose Reconstructions?

HHS received various comments concerning who is eligible for dose reconstructions and the circumstances under which NIOSH would conduct a dose reconstruction.

Several commenters suggested there may be covered employees who require dose reconstructions who do not fit

within the three statutorily-prescribed groups specified under section 7384n(d)(1) of EEOICPA and reiterated under § 82.3 of this rule to be eligible for dose reconstructions. The commenters recommended the rule should include all individuals filing compensation claims for cancer under EEOICPA.

EEOICPA covers two groups of claims seeking compensation for cancer: claims seeking compensation under provisions of the Special Exposure Cohort and all others. Claims seeking compensation in the former group do not require dose reconstructions for DOL to adjudicate and hence DOL will not refer these claims to NIOSH for a dose reconstruction. Thus, the HHS rule should not be broadened to include all claims seeking compensation.

Several other commenters stated that EEOICPA did not require dose reconstructions for employees who were monitored and for whom DOE has complete dose records. One commenter indicated that DOL should be able to use the dose of record from DOE instead of obtaining a dose reconstruction from NIOSH when the dose of record is sufficiently high to qualify the claimant for compensation.

NIOSH is implicitly required by EEOICPA to evaluate the dose of record of every eligible claim, since without such an evaluation it could not be determined whether the monitoring data for the individual are complete and adequate. Moreover, the data provided in the dose of record from DOE are not in a form that can be used by DOL to calculate probability of causation. Nonetheless, HHS agrees that when the dose of record is itself very high, NIOSH should not expend resources on a dose reconstruction needlessly or cause unnecessary delay in DOL's adjudication of the claim. For this reason, the rule includes efficiency measures under § 82.10 to limit the extent of the dose reconstruction depending on the circumstances. In the example given by the commenter, if the dose of record was evidently high enough to qualify the claimant for compensation, NIOSH would greatly abbreviate its effort, so that the claimant is not unnecessarily delayed in awaiting DOL to determine probability of causation and complete adjudication of the claim.

One commenter questioned whether the definition of a ''covered employee'' under § 82.5 is sufficiently inclusive. HHS specified more narrowly than EEOICPA that a covered employee, for the purposes of the HHS rules, is a DOE or AWE employee for whom DOL has requested HHS to perform a dose reconstruction.

This distinction results practically from the separate responsibilities of DOL and HHS in implementing EEOICPA. DOL is solely responsible for initially reviewing each claim, evaluating whether the claim represents a covered employee with a covered illness, and determining whether or not the claim requires a dose reconstruction. The only claims DOL will forward to HHS for dose reconstructions are those for a cancer not covered by provisions of the Special Exposure Cohort. Hence, HHS retains its proposed definition in this rule to be clear that NIOSH will only conduct dose reconstructions under EEOICPA for the subset of claims submitted by DOL to HHS for dose reconstructions. This is intended to avoid the possible confusion and delay that would arise if claimants were to directly submit to NIOSH requests for dose reconstructions.

One commenter recommended a change to the definition given in this rule for Atomic Weapons Employer (AWE). The commenter recommended the definition include entities that ''handled'' material that emitted radiation and include entities that processed, produced, or handled radiation-emitting equipment as well as material.

The definition for AWE in the rule was established by Congress in EEOICPA. For a conclusive interpretation, the commenter should contact DOE, which is the only federal agency authorized to designate AWEs.

One commenter recommended that HHS explain which employees at DOE or AWE facilities are not covered by EEOICPA and hence not eligible for dose reconstructions. The commenter specified Department of Defense employees as an example.

As explained above, HHS does not determine whether an individual is a covered employee under EEOICPA. This is a responsibility of DOL. Potential claimants for individuals who worked at DOE or AWE facilities should consult with DOL to determine whether the individual might be a covered employee.

E. Establishing a Time Limit for Dose Reconstructions

One commenter recommended HHS consider establishing a time limit for dose reconstructions.

HHS is especially interested in ensuring that dose reconstructions are conducted on a timely basis, to allow the timely adjudication of claims by DOL. To this end, NIOSH is establishing performance standards for dose reconstructions that include time criteria for completion of dose reconstructions and for critical intermediate steps. And NIOSH is establishing capacity to conduct a high volume of dose reconstructions.

It would not be in the interests of claimants, however, to establish rigid time requirements for dose reconstructions. A variety of parameters will affect the speed with which a dose reconstruction can be completed; these are not controlled or determined by NIOSH. For example: the first dose reconstructions conducted for employees at a particular facility or operation within a facility are likely to take longer than subsequent dose reconstructions, since a substantial factual basis relevant to the subsequent dose reconstructions will be established by the initial dose reconstructions; some facilities will have better organized and more accessible records than other facilities, making dose reconstruction more efficient; individual claims will require dose reconstructions that differ in complexity, depending on the employment history, the adequacy and completeness of the records available, and the radiation dose levels indicated by the records initially available; and the overall dose reconstruction program will become more efficient over time, as experience and data accrue to NIOSH, reducing the data collection phase of subsequent dose reconstructions.

F. Use of Records and Information

HHS received a variety of comments concerning the use of records and information for dose reconstructions.

Several commenters disagreed with HHS in requiring under § 82.10(e) that for NIOSH to use information provided by the claimant, the information must be supported by ''substantial evidence,'' and not be ''refuted by other evidence.'' The commenters interpret the substantial evidence provision as placing the burden of proof on the claimant. They interpret the refutation provision as unfairly favoring information from DOE over information from the claimant.

The provision concerning substantial evidence, when considered completely, should not place an unreasonable burden of proof on the claimant. The provision explains a variety of parameters that NIOSH will evaluate in determining whether information provided by the claimant is supported by substantial evidence. NIOSH, rather than the claimant, has the burden of conducting this evaluation, and most of the parameters relate to information held by NIOSH, rather than supplied by the claimant. The claimant may be requested to provide medical records, if relevant. Likewise, the claimant may be

able to identify coworkers who could confirm certain information provided by the claimant.

The commenter did not indicate that any of the parameters NIOSH will consider, in evaluating information provided by the claimant, are unreasonable or unfair. Moreover, it would be irresponsible for NIOSH to make use of information provided by the claimant without considering its validity. In many cases, claimants and coworkers will be recalling procedures and conditions and incidents that occurred decades earlier.

Similarly, HHS finds it reasonable to omit the use of information provided by a claimant that is refuted by other, more persuasive evidence available to NIOSH. If, for example, NIOSH establishes the period when a certain process was undertaken at a facility, based on a complete administrative record (purchase orders, shipment logs, production figures, etc.), this record might refute a claimant's recollection that a different process operated during this period.

This provision does not, as suggested by the commenter, unfairly favor DOE information over that of the claimant. The dose reconstruction program established under this rule includes major elements to evaluate the adequacy and completeness of DOE or AWE records. A key purpose of NIOSH interviewing claimants and co-workers and making use of records from research and other sources, is specifically to support such an evaluation.

Several commenters recommended NIOSH determine the availability of records from DOE facilities independently of DOE, versus relying on certifications by DOE as provided for under § 82.10(h).

As discussed in the rule, NIOSH will be determining the availability of records from a variety of sources, including NIOSH-conducted and NIOSH-funded research, other researchers with experience at DOE facilities, and interviews with claimants and coworkers. Nonetheless, the DOE certifications are an important measure to assist NIOSH in ensuring it has employed as complete a record as possible in each dose reconstruction.

Several commenters recommended NIOSH should be required to make use of data from NIOSH records in a dose reconstruction, versus having the option to do so, as provided for under § 82.10 (a).

NIOSH should not be compelled to make use of records from sources other than DOE in all dose reconstructions. There will be many dose reconstructions for which the records provided by DOE will be preferable for use in the dose reconstruction. NIOSH must have the discretion to use records from whichever source will support the completion of the highest quality dose reconstructions and timely dose reconstructions under efficiency measures, when applied.

One commenter interpreted the text of § 82.10(a) to limit the relevant types of information NIOSH would seek from DOE. The commenter recommended that this text be expanded to explicitly include all types of records, such as information on contamination incidents and work restrictions.

HHS provides substantial detail under § 82.14 on the types of data NIOSH will use, as necessary, in dose reconstructions. The text addressed by the commenter is intended to be general and inclusive.

G. Claimant and Coworker Interviews

HHS received several comments concerning the claimant and coworker interviews covered under § 82.10 of the rule.

One commenter sought clarification about whom would be interviewed when the claimant is a survivor.

When the claimant is a survivor, the claimant and one or more coworkers of the deceased employee may be interviewed, as necessary and possible. The interviews of coworkers are intended to substitute for information that would have been available from the employee.

One commenter recommended that the claimant have multiple rounds of the closing interview, if the claimant provides additional information at these interviews that might be incorporated into the dose reconstruction.

NIOSH will continue the closing interview until it is complete. The use of the term ''interview'' (singular) in this rule, for both the initial and closing interviews, is intended to cover as many interview sessions as required. NIOSH anticipates that the initial interviews will often be conducted over more than one session, allowing the claimant or coworker to recall information or, in the case of ill and aged individuals, to rest and recover between sessions. When claimants provide new information or notify NIOSH of the intent to obtain new information in closing interviews, these too will require multiple sessions to conclude.

One commenter noted that the interviews will not meet the therapeutic or social counseling needs the claimant might require as a cancer patient.

HHS agrees with the commenter. The interviewers will be sensitive to the perspectives of claimants but they will not be trained as counselors or therapists. This is outside the scope of these interviews.

H. Evaluating Exposure Characteristics

HHS received one comment regarding § 82.10(i), which describes generally that NIOSH will characterize internal and external exposure environments for parameters known to influence dose, as necessary, in conducting the dose reconstruction. A parameter for external dose is the non-uniformity and geometry of the radiation exposure, which relates to the fact that the location of a radiation source in relation to the worker can affect the level of exposure recorded by their radiation monitoring badge. The commenter asks how NIOSH will assess this factor.

NIOSH will use process information available from DOE, an AWE, and/or the claimant or coworkers to locate the worker in relation to the radiation source. NIOSH will use this information, along with conversion factors published by the ICRP and the International Commission on Radiation Units and Measurements, to calculate the level of radiation dose received based on the level recorded by the radiation badge. More details on this procedure will be provided in the NIOSH Implementation Guide for External Dose Reconstruction under EEOICPA, which will be available through the internet or direct addresses for NIOSH provided above.

I. Use of ICRP Models

HHS received various comments concerning the use of ICRP models for calculating internal radiation doses.

Most of the comments concerned differences between the use of the current ICRP models under this rule and the use of older ICRP models applied in DOE and other U.S. radiation protection programs. Commenters indicated that some of the older ICRP models produce higher dose estimates than current models, whereas other older ICRP models produce lower dose estimates than the current models. One commenter asserted these differences extend from one to two orders of magnitude (*i.e.,* a difference of 10—100 times). Several commenters recommended that NIOSH use the dose of record, calculated using the older ICRP models, when these would produce a higher dose estimate. Another commenter recommended that NIOSH not diverge from the models used by DOE for radiation protection programs. Finally, one commenter recommended that NIOSH explain to claimants the difference between the doses estimated by NIOSH and the doses of record.

As explained in the interim final rule and above, NIOSH is using current ICRP models because they represent improvements in the science of internal and external radiation dosimetry compared to older ICRP models. It is true that in some cases the current models will reduce the dose calculated and in other cases they will increase the dose calculated, but the differences should typically be far less than stated by the commenter. In any event, the estimates are more accurate when based on the current ICRP models.

Moreover, it is not possible for NIOSH to use the dose of record from DOE, nor will it generally be possible to even compare the dose of record with the dose estimates produced by NIOSH. In general, the dose of record is not organ-specific, is not reported for the different forms of radiation required as an input for NIOSH-IREP, and applies to different time periods than the period from first exposure to the diagnosis of cancer, including 50 year committed doses, which are not useful for purposes of calculating probability of causation. These differences will be explained to the claimant in the final dose reconstruction report and during their closing interview.

Several commenters recommended that NIOSH not rely exclusively on ICRP models, but allow the use of individual-specific models when available data are adequate.

In rare individual cases the ICRP models will not be applicable, such as for workers with chronic emphysema, or who have undergone chelation therapy, or had their thyroids removed. Singular exposures might also fall outside the scope of ICRP models, such as a worker that inhaled metal tritides. In these cases, NIOSH will have to use alternate models or modify existing models. In all other cases, NIOSH will consistently apply the ICRP models, which are widely accepted and extensively peer-reviewed.

One commenter questioned how NIOSH will handle cases for which the cancer is in a tissue not covered by existing ICRP models.

In these cases, NIOSH will use the ICRP model that best approximates the model needed, while giving the benefit of the doubt to the claimant. For internal exposures, NIOSH will select the highest dose estimate from among the modeled organs or tissues that do not concentrate the radionuclide. This provision has been added to the rule under § 82.18(b).

One commenter questioned whether NIOSH intends to use original urine and fecal data and lung count data to recalculate the employee's dose.

As outlined in this rule, NIOSH will be using original source data from DOE. These procedures are explained in detail in the NIOSH implementation guides for dose reconstruction, available from NIOSH through the internet or directly from the addresses provided above.

One commenter recommended against using the ICRP weighting factors provided in Table 1 of § 82.10(j) of the interim rule, which can differ from the weighting factors used by DOE in its radiation protection program. Another commenter suggested NIOSH obtain a peer-review of these weighting factors. And a third suggested HHS remove Table 1 from the rule, since this would lock HHS into using these current ICRP weighting factors, some of which could change in future ICRP udpates.

As discussed above with respect to use of ICRP models, NIOSH is using current ICRP weighting factors because they represent the best, thoroughly peer-reviewed, science. HHS agrees with the recommendation to remove Table 1, so that NIOSH can use new weighting factors at such time as ICRP updates them, without requiring HHS to re-promulgate a section of this rule. This is consistent with the overall construction of this rule, which allows NIOSH to update underlying scientific elements through a public process that does not require rulemaking.

J. Use of Efficiency Measures

HHS received several comments addressing the use of efficiency measures under § 82.10k this rule to enable NIOSH to complete dose reconstructions efficiently and on a timely basis for claimants. These measures are discussed in the summary of rule below.

One commenter recommended against use of these measures out of concern that resulting dose reconstructions might provide the basis for appeals by claimants whose claims are denied. The same commenter was also concerned these dose reconstructions might cause difficulties if they were used as evidence in litigation between private parties.

It is highly likely some denied claimants will contest the results of their dose reconstructions, regardless of whether or not their doses were reconstructed using efficiency measures. DOL has established an administrative process for claimants to object to recommended decisions under 20 CFR Part 30. The public should recognize, however, that the use of efficiency measures in these cases means the claim has been adjudicated using dose levels estimated on a worst-case basis. In other words, the claim has been assigned dose estimates that are likely to be substantially higher than the doses actually incurred by the covered employee. This same understanding, which will be clearly explained in the NIOSH dose reconstruction report for these claims, will be important to any litigation that might arise between private parties. HHS does not believe that the dose reconstruction results should be used for any purpose other than the probability of causation calculations required under EEOICPA.

Several commenters recommended against NIOSH considering the level of probability of causation associated with dose information on claims, a recommendation which, if accepted, would effectively preclude NIOSH from applying any efficiency measures. One commenter indicated that consideration of probability of causation by NIOSH would detract from the credibility of NIOSH dose reconstructions. A second commenter reasoned it would be presumptive for NIOSH to evaluate probability of causation, when this is the role of DOL later in the adjudication process.

NIOSH will not consider probability of causation on a routine basis, only for claims that evidently involve very high or low doses, as explained in the interim rule and this final rule. As HHS has explained above, without the use of efficiency measures HHS cannot complete dose reconstructions on a timely basis, which would harm all claimants, whether or not their claims are accepted. Furthermore, for the claims in which efficiency measures will be applied, it would be disingenuous to suggest NIOSH does not recognize the implications for probability of causation of the high or low doses that are evident.

One commenter requested HHS define the meaning of the phrase under 82.10(k): ''extremely unlikely to produce a compensable level of radiation dose.'' This phrase is used in the provision allowing the use of worst-case assumptions as an efficiency measure only for claims involving uncompensably low doses of radiation.

Dose estimates sufficiently high to qualify a claimant for compensation definitively cannot be based on worst case assumptions employed as an efficiency measure to abbreviate research and analysis. Consequently, HHS has changed this phrase to be definitive. This provision now reads: ''Worst-case assumptions will be employed * * * to limit further research and analysis only for claims for which it is evident that further research and analysis will not produce a

compensable level of radiation dose (a dose producing a probability of causation of 50% or greater), because using worst-case assumptions it can be determined that the employee could not have incurred a compensable level of radiation dose.''

K. Types of Information To Be Used

HHS received various comments addressing the types of information to be used by NIOSH in dose reconstructions. These comments primarily address provisions under § 82.14 of the interim rule and this final rule.

Several commenters recommended NIOSH include additional items under several of the types of information listed in § 82.14. One of the commenters suggested NIOSH add an ''other'' option for each type of information, rather than specify each possibility.

HHS has added an appropriate option for other, unspecified examples of information that NIOSH might use, where needed. This will avoid the risk of omitting a type of information that has not been considered but might be relevant.

One commenter questioned how NIOSH would determine the radiation type using the summary radiation records produced by DOE.

NIOSH is obtaining and using primary data on radiation sources, exposures, and doses, rather than the summarized data reported to employees. In cases in which NIOSH cannot identify the type of radiation, NIOSH will assume the radiation is of a type consistent with existing information and which results in a higher probability of causation, compared to the alternatives.

One commenter recommended that NIOSH not assume that neutron exposures are chronic doses and that photon exposures are acute doses.

The methods under this rule do not include any presumption of chronic or acute doses based on the radiation type. Doses will be characterized as chronic or acute based on the information available. If, however, NIOSH does not have information that distinguishes between chronic and acute doses, NIOSH will assume the type of dose that would result in a higher probability of causation.

Several commenters recommended against HHS including medical screening x rays administered to nuclear weapons employees as a condition of employment. Similar comments were received on the HHS probability of causation notice of proposed rulemaking (42 CFR Part 81), as well. Commenters argue that the benefit of these exposures justifies their attendant risks, and therefore they should not contribute to the acceptance of a claim for compensation.

HHS will not exclude radiation exposures resulting from these medical screening x rays. The important factor in this decision is that the exposures were incurred ''in the performance of duty,'' as specified by EEOICPA. The employees were required to receive these x ray screenings and hence were exposed to radiation in the performance of duty.

One commenter questioned how NIOSH would account for the doses associated with x ray administrations that were unsuccessful and thus had to be repeated, resulting in multiple doses. Similarly, the commenter asked whether individual factors affecting the x-ray dose would be taken into account, such as the weight of the employee.

The rate of repeat exposures associated with unsuccessful administrations has been evaluated in the scientific literature. NIOSH will account for these rates in the uncertainty distribution for the medical x-ray dose. Generally, NIOSH will also use this approach to account for variation in individual factors affecting radiation dose. NIOSH will make use of information on individual factors when available and feasible, but expects such circumstances will be unusual.

One commenter suggested HHS consider including the doses from diagnostic x rays that employees received in the treatment of work-related injuries.

EEOICPA authorizes HHS to account only for radiation exposures incurred by an employee in the performance of duty. The intent of Congress was to provide compensation for cancers arising from the unique radiation exposures incurred by covered employees in the performance of duty for U.S. nuclear weapons programs. Radiation exposures associated with medical treatment of work injuries are not incurred in the performance of duty and are not unique to the experience of nuclear weapons employees.

Several commenters recommended NIOSH include radiation exposures to medical staff serving DOE or AWE facilities.

NIOSH will include all radiation exposures incurred by covered employees in the performance of duty.

Several commenters recommended NIOSH estimate non-covered radiation doses from community and personal exposures (e.g., sun, radon, diagnostic and therapeutic exposures in medical care). The commenters intended that DOL would adjust (reduce) probability of causation calculations to account for these non-covered exposures.

The risks associated with these community and non-occupational exposures are already accounted for in the risk models DOL will use to calculate probability of causation. These are inherent in the background rates for cancer. DOL will not have access to personal data or related adjustment factors for the risk models that would be required to account for individual variation with respect to these non-occupational radiation exposures.

One commenter indicated that some of the information, particularly process information, that may be required by NIOSH for dose reconstructions will require substantial labor for DOE and its contractors to provide. The commenter indicated that DOE has not funded its contractors to provide this information and, hence, questions whether such information will be made available.

HHS is aware that this program will make substantial informational demands on DOE and consequently on DOE contractors. NIOSH has experience obtaining information of types specified in the rule from DOE contractors for health studies on DOE populations. HHS, DOE, and DOE contractors are currently working together to collect records presently needed for dose reconstructions and to improve record and information collection procedures for dose reconstructions. The goal of the agencies is to establish procedures that are practical and efficient while ensuring NIOSH can complete high quality dose reconstructions on a timely basis.

L. Evaluating the Completeness and Adequacy of Records

HHS received several comments regarding the procedures by which NIOSH is evaluating the completeness and adequacy of records available for a dose reconstruction, under provisions of § 82.15.

One commenter recommended the rule address the problem of incomplete dose records.

This is one of the principal reasons for conducting a dose reconstruction. The interim final rule and this final rule directly address this issue under § 82.15. NIOSH is determining when dose records are incomplete through comparisons between records available from DOE or the AWE and information provided by the claimant, coworkers, and the variety of other sources available. Sections 82.2, 82.10, 82.16, and 82.17 generally address how NIOSH will conduct dose reconstructions making use of limited records and information.

Several commenters questioned how NIOSH would weigh potentially conflicting evidence from different sources.

NIOSH will conduct these evaluations on a case-by-case basis, evaluating the weight of the evidence from different sources. The NIOSH evaluation will be fully documented in the NIOSH dose reconstruction report provided to the claimant, DOL, and DOE. There are no strict criteria to be applied to this purpose. As § 82.10(e) states, NIOSH will accept claimant information supported by substantial evidence, unless ''refuted'' by other evidence, which in the case of conflicting evidence places the burden on other sources to refute the claimant's information.

For example, a claimant might assert involvement in a contamination incident that cannot be confirmed by DOE records addressing the incident. NIOSH might accept this assertion if it is consistent with work history information, claimant provided details about the incident, co-worker recollections, or other investigations of the incident (*e.g.,* during research). Evidence that certain DOE records are incomplete or inaccurate is likely to weigh against reliance on such records.

As NIOSH develops approaches to address conflicting evidence in dose reconstructions, NIOSH will document those that can be incorporated into standard operating procedures. NIOSH will make these available to the public through the NIOSH addresses provided above.

One commenter raised concerns about possible recall difficulties and bias of employees with respect to past exposure incidents and conditions.

It is well recognized from health, behavioral, and social research that there are substantial limitations and variation in the ability of people to accurately recall past events, and that these limitations generally increase with the time elapsed since the past event. However, all of the sources of information available to NIOSH in conducting dose reconstructions potentially involve substantial limitations. To conduct dose reconstructions, NIOSH will apply procedures available to it to mitigate these limitations to the extent possible. To improve the recall of employees, NIOSH will inform the employee of information available from employment and dosimetry records. NIOSH will also compare information obtained from the employee with other sources of information, such as coworkers or DOE records.

One commenter recommended that the rule require concurrence with NIOSH by DOE and its contractors when NIOSH finds that individual monitoring data from DOE records are either incomplete or inadequate. The commenter was concerned that the complex information available from DOE might be misinterpreted by NIOSH.

Under EEOICPA, NIOSH alone is authorized to determine which data to use in a dose reconstruction and how to interpret them. NIOSH will work closely with DOE and its contractors, however, to obtain the most useful and complete data available, which will ensure dose reconstructions are of the highest possible quality.

M. Remedying Limitations of Monitoring and Missed Dose

HHS received various comments regarding how NIOSH would remedy limitations of monitoring and missed dose, including unmonitored doses. These comments relate to provisions of the interim final rule and this final rule under §§ 82.16–82.18.

Several commenters recommended NIOSH use coworker external monitoring data for a similarly exposed worker whose records omit such information. One of the commenters recommended that NIOSH preferentially use coworker data over data from area monitoring.

The interim final rule and this final rule provide for NIOSH to use coworker data under §§ 82.16 and 82.17. Use of coworker data depends on its availability and the extent to which coworkers shared similar exposures. Nonetheless, NIOSH will review area monitoring data to evaluate the adequacy of the personal dosimetry.

Several commenters recommended NIOSH consider all relevant data, not only air sampling results, to estimate internal doses when biomonitoring data are unavailable. Another commenter indicated concern about the quality of early biomonitoring data.

HHS agrees with the comments and recognizes the limitations of early biomonitoring data, which can be addressed. HHS has revised § 82.18 to reflect the intent of NIOSH to consider all sources of relevant data to interpret or substitute for biomonitoring data.

Several commenters advised concerning § 82.16 that NIOSH cannot estimate missed dose by summing potential doses using the limit of detection of monitoring equipment. Missed dose is a term applied to the dose that is potentially undetected because of the detection limits of monitoring technology and procedures.

Indeed, as indicated in this section, NIOSH will not sum potential doses to estimate missed dose; only to estimate the upper limit of missed dose. Missed dose will be evaluated statistically using standard dose reconstruction procedures, as detailed in the NIOSH implementation guide for reconstructing external doses.

The commenters also remarked that NIOSH should consider the reason for missing records and generally the problem of noncompliance with official DOE procedures.

These issues are important but separate, concerning the completeness and adequacy of records, and are addressed under § 82.15.

One commenter indicated concern that NIOSH might indiscriminately assign missed doses to employees, even if their work did not require them to enter areas of potential radiation exposure. Similarly, the commenter was concerned that NIOSH might not understand that certain employees were not monitored because they did not have potential radiation exposure.

NIOSH is experienced in dose reconstruction and fully understands the variety of conditions of work at DOE and other nuclear weapons production facilities. NIOSH will evaluate the potential for radiation exposure in the work activities and locations of the employee and will not indiscriminately estimate missed dose for periods when monitored workers lack detected exposures, or indiscriminately estimate doses for unmonitored workers. Dose reconstructions will be based on the conditions and radiation levels of the areas in which the individual worked.

One commenter recommended HHS identify radioactive contamination surveys as a source of information that may be used to supplement or substitute for individual monitoring data, under § 82.17.

HHS has revised this section of the rule to explicitly include these surveys, as intended.

N. Accounting for Uncertainty

HHS received several comments concerning issues of statistical uncertainty and its ramifications for the dose reconstructions.

Several commenters recommended NIOSH characterize uncertainty over the entire period of interest rather than estimating uncertainty parameters for each annual dose estimate. They reasoned that this would reduce uncertainty.

NIOSH–IREP requires annual dose estimates with individual uncertainty parameters to calculate probability of causation. Since NIOSH–IREP uses

Monte-Carlo techniques to combine uncertainties, the propagated uncertainty based on annual uncertainties will be less than if the annual uncertainties were simply added. This issue will be addressed in detail in the NIOSH implementation guides.

Several commenters indicated the dose reconstructions would be unfairly biased in favor of internally exposed workers. The commenters assumed there would be more uncertainty associated with internal doses.

The extent and characteristics of uncertainty will differ on a case-by-case basis, depending on the completeness and adequacy of records and monitoring. Uncertainty will not always be greater for internal dose estimates. It is true, however, that a substantial degree of uncertainty is inherent to internal dose calculations. This is a scientific limitation without any remedy.

Several commenters questioned at what point uncertainty associated with a dose reconstruction would be too great to be considered ''reasonable.'' EEOICPA requires ''reasonable estimates'' of radiation doses. 42 U.S.C. 7384n(d)(1).

As explained above, HHS interprets this term to mean estimates calculated using a substantial basis of fact and the application of science-based, logical assumptions to supplement or interpret the factual basis. Claimants will in no case be harmed by any level of uncertainty involved in their claims, since assumptions applied by NIOSH will consistently give the benefit of the doubt to claimants. Hence, the level of uncertainty is not an issue whenever there is a sufficient factual basis to establish the radiation source type and quantity and a basic understanding of the process in which the employee worked. This information can provide the basis for a reasonable estimate. When this basic information is lacking, however, then NIOSH may not be able to establish reasonable estimates. As discussed below, when NIOSH lacks sufficient information to complete dose reconstructions, claimants will be informed of procedures for petitioning HHS under the proposed Special Exposure Cohort procedures, which will be published soon in the **Federal Register**.

O. Completing and Reporting Dose Reconstructions

HHS received several comments concerning the procedures by which NIOSH completes and reports dose reconstructions. These address §§ 82.25 and 82.26 of the interim final rule and this final rule.

One commenter recommended HHS establish a procedure for claimants who refuse to certify that they have completed providing information for the dose reconstruction, by refusing to sign the form OCAS–1. NIOSH requires this certification to close the record and conclude the dose reconstruction.

The interim final rule and this final rule include a provision under § 82.10(n) to address these circumstances. Claimants will have at least 60 days to sign OCAS–1. After the 60 days and after notifying the claimant or the authorized representative, NIOSH will administratively close the dose reconstruction for a claimant who, without good cause as described below, steadfastly refuses to sign OCAS–1. This provision will not be applied, however, while a claimant is attempting to obtain additional information relevant to the claim, notified NIOSH of this fact, and clearly specified the information being sought.

One commenter recommended that NIOSH clarify that internal doses will only be estimated for the primary cancer sites covered in the claim.

HHS agrees with this comment and has clarified the relevant provision under § 82.26(b)(2).

Several commenters recommended NIOSH not report separate doses for different radiation types, dose patterns, and other parameters, because these specifics may not be meaningful to claimants.

NIOSH must provide this detailed information to DOL to calculate probability of causation. HHS believes this information will also be meaningful to claimants, since it is the precise basis for their probability of causation determination by DOL. NIOSH will explain this information to the claimant in the final dose reconstruction report and the closing interview, as provided for under §§ 82.10 and 82.26 of the interim final rule and this final rule.

One commenter requested that HHS define the term: ''as necessary,'' used under § 82.26(b)(3) with respect to specifying uncertainty distributions associated with each dose estimated. The term is used in this provision because uncertainty distributions will not be applied to all doses estimated. Doses estimated using worst-case assumptions will not involve uncertainty.

Several commenters questioned the basis for NIOSH notifying claimants of the results of its dose reconstructions on behalf of DOE, as indicated in the interim final rule. EEOICPA includes a requirement that DOE inform employees of the results of dose reconstructions under EEOICPA. 42 U.S.C. 7384n(e)

HHS has proposed to DOE that it would inform claimants of dose reconstruction results on behalf of DOE to avoid duplication of effort and an unnecessary expenditure of federal resources. This arrangement can be established by agreement between the two federal agencies and would fulfill the statutory requirement. DOE may decide, however, to reserve this authority to itself and inform its employees independently of NIOSH. HHS has omitted the term ''on behalf of DOE'' in this final rule to allow DOE to reserve this authority to itself.

P. Reviews of Dose Reconstructions or Dose Reconstruction Methods

HHS received several comments concerning the review of NIOSH dose reconstructions.

One commenter recommended HHS describe the review process at NIOSH, as provided for under § 82.27, in greater detail.

The rule includes additional provisions describing that reviews can be initiated by NIOSH as well, as discussed above. HHS has also added provisions to this section to clarify that NIOSH will report on the review to the claimant, DOL, and DOE, describing the basis for the review, the methods applied and the results. However, HHS has not specified the details of review processes. These are likely to vary substantially, depending on the basis for the review and the issues that must be addressed. Review processes are likely to vary from simple, in which a NIOSH staff person or contractor makes identified technical or factual corrections, to extensive, requiring previously uninvolved NIOSH employees, contractor staff, or independent experts to collect additional data and re-conduct elements of a dose reconstruction. Standard operating procedures for different types of reviews will be established as needed, and made available to the public. In every case, however, it will be in the agency's interest to conduct an appropriate and credible review, since the review will be examined by DOL in order to exercise its discretion concerning whether the claim should be reopened.

One commenter requested clarification of the review rights of DOL with respect to NIOSH dose reconstructions. Specifically, the commenter appeared to seek further explanation of the provision under § 82.27(a) of the interim final rule and this final rule, which reads as follows: ''(2) although the methodology

established by HHS under this Part is binding on DOL, DOL may determine that arguments concerning the *application* [emphasis added] of this methodology should be considered by NIOSH.''

This provision sets forth DOL's regulatory description of the scope of the review performed by DOL in considering objections to recommended decisions. Further clarification of that provision should come from DOL.

One commenter recommended that NIOSH provide the draft dose reconstruction report to DOE for its review, prior to concluding the dose reconstruction. The commenter indicated that the familiarity of DOE with its own records makes it uniquely able to review the use of its data in the dose reconstruction.

Under EEOICPA, Congress and the President specifically intended that the role of DOE in dose reconstructions be limited to providing records and information, and that an agency in a separate federal department conduct the dose reconstructions. The intent was to ensure that the agency conducting the dose reconstructions would have no actual or perceived interest in their outcomes. HHS has not authorized DOE to review NIOSH dose reconstructions because such a measure would conflict with this intent. The public should also be assured that NIOSH, which has the lead federal role in health research on DOE employees, is highly expert on DOE operations, records, and dosimetry practices.

One commenter recommended this rule specify the percentage of NIOSH dose reconstructions to be reviewed by the Advisory Board on Radiation and Worker Health. A second commenter recommended this rule specify the procedures to be applied by the Board in their review.

As described above under the discussion of statutory provisions related to this rule, EEOICPA requires the Board to conduct an independent review of a sample of NIOSH dose reconstructions. 42 U.S.C. 7384n(d). Since this review is specified to be independent, the Board, rather than HHS, must determine the procedures for the Board's review of NIOSH dose reconstructions. Moreover, this level of autonomy is important for the credibility of the review.

One commenter recommended NIOSH obtain peer review of the detailed dose reconstruction methods used under this rule but not specified in this rule. These methods are described in the NIOSH implementation guides for dose reconstructions and will be further specified as NIOSH develops standard operating procedures, as needed.

NIOSH is obtaining peer review of specific implementation procedures for dose reconstructions by the Advisory Board on Radiation and Worker Health, which is authorized under EEOICPA to review these methods. 42 U.S.C. 7384n(d). In addition, NIOSH will obtain reviews from independent subject matter experts as necessary, and may also seek reviews periodically by other standing scientific bodies, such as the National Academy of Science.

Q. When Information Is Inadequate To Complete a Dose Reconstruction

HHS received several comments concerning NIOSH actions when it cannot complete a dose reconstruction due to inadequate data, as provided for under § 82.12 of this rule.

Several commenters requested HHS to define the circumstances under which information would be inadequate to complete a dose reconstruction. One of the commenters recommended HHS establish a ''checklist'' of potential informational sources that would serve as standardized criteria for determining whether information is adequate to complete a dose reconstruction.

HHS does not expect this situation to arise frequently. In some cases, limited information about the radiation source term (type and quantity of radioactive material) and the process in which it was used, without any individual monitoring records, will be sufficient to complete a dose reconstruction, particularly when the potential level of radiation that was emitted is extremely low. In these cases, NIOSH can make use of worst case assumptions to fully account for the highest possible radiation doses that might have been incurred.

Simplifying assumptions become more difficult to apply, however, when the potential level of radiation exposure for an individual ranges greatly, particularly when they range from low levels to potentially compensable levels (levels that produce a probability of causation of 50% and above). In these circumstances, the ability of NIOSH to complete the dose reconstruction depends on the extent and quality of information available to substitute for monitoring data. This can be readily defined on a case-by-case basis but not using rigid criteria; the potential circumstances are not readily foreseeable. As explained in the interim final rule and in this final rule, when NIOSH cannot complete a dose reconstruction, the basis for this result will be clearly explained in a report to the claimant, DOL, and DOE.

When NIOSH cannot complete a dose reconstruction, one commenter recommended HHS automatically provide any necessary forms required by the claimant to file a petition for addition of a class of employees to the Special Exposure Cohort. A second commenter recommended HHS file the petition on behalf of the employee.

HHS agrees with the proposal to supply the claimant with information needed to file a petition with HHS, and has included this as a new provision in the final rule. HHS will not, however, file a petition to HHS on behalf of the claimant. EEOICPA requires that a petition be filed by a class of employees. 42 U.S.C. 7384q.

R. Definitions of Terms

One commenter recommended HHS provide a more specific definition in the rule for the term ''uncertainty distribution.''

This definition is intended to be general. Various forms of uncertainty distributions are relevant to the definition, including unique, unspecifiable forms derived from Monte Carlo simulations.

S. Special Exposure Cohort

HHS received several comments that provide recommendations, criteria, or concerns related to adding members to the *Special Exposure Cohort* established under EEOICPA. These comments fall outside the scope of this rule and address related but separate procedures to be established by HHS.

As discussed above, HHS is proposing procedures by which it will consider petitions by classes of employees at DOE or AWE facilities to be added to the cohort, with the advice of the Advisory Board on Radiation and Worker Health. These procedures will be published soon in the **Federal Register**. The proposed HHS procedures and their accompanying explanation will address the comments received and directly solicit additional public comments, which HHS will fully consider in establishing final procedures.

III. Review and Recommendations of the Advisory Board on Radiation and Worker Health

HHS requested the Advisory Board on Radiation and Worker Health to review these HHS methods of dose reconstruction. The Board reviewed the methods during public meetings on January 22–23 and February 13–14, 2002. In preparation for the meetings, the Board members individually reviewed the interim final rule as well as the HHS notice of proposed

rulemaking proposing guidelines for determining probability of causation (42 CFR Part 81), which will be applied by DOL using the radiation doses estimated under these methods. The members also reviewed public comments on these rules. In addition, NIOSH staff members gave formal presentations on the HHS rules, implementation procedures, and related issues during the Board meetings. The transcripts and minutes of these meetings are included in the NIOSH docket for this rule and are available to the public.

All of the Board members participated in the review of these guidelines and they unanimously concurred in establishing the Board findings and recommendations. The Board provided general findings addressing the general questions for public comment HHS identified in the notice for proposed rulemaking. The Board also provided recommendations addressing details of the rule. The findings and recommendations are provided below, together with responses by HHS to the recommendations:

A. General Comments of the Board Responding to HHS Questions

''Interim proposed rule 42 CFR, part 82, makes appropriate use of current science in reconstruction of radiation dose scenarios to the extent practicable. The Board recognizes that if the efficient and expeditious consideration of claims is to be made, absolute precision is not possible. The methods proposed are intended to result in dose estimates favorable to the claimants and are appropriate to the occupational illness compensation program envisioned by the Energy Employees Occupational Illness Compensation Program Act (EEOICPA).

The process for involving the claimant is fair and provides multiple opportunities for interaction with the involved agencies. Indeed, in cases where acceptably dependable personal exposure data do not exist, NIOSH will utilize other sources of information as the basis for dose reconstruction. This approach unavoidably introduces additional uncertainty into the calculation of dose. However, we view the proposed methods as being appropriate for the available information. There will be circumstances where NIOSH will not be able to estimate the dose with sufficient accuracy. Those circumstances need to be clarified in the implementation of the regulation and in the Board's review of NIOSH's dose reconstruction work. Groups whose exposure cannot be estimated with sufficient accuracy may be candidates for the Special Exposure Cohort.''

B. Specific Comments and Recommendations of the Board:

Board Comment #1: ''The Advisory Board recommends that Section K of Part III, 'background' concerning changes to scientific elements underlying the dose reconstruction process be moved to the main body of the Rule so as to formalize the updating process including the role of the Advisory Board. The rule does an admirable job of providing an objective process for conducting dose reconstruction. However, the assessment of the adequacy of the exposure information will involve professional judgment, and thus, some subjectivity. The Board plays an important role through its review of such decisions on dose reconstructions, and that role needs to be included in the main body of the Rule. Although this role is included in the Preamble 'Background' (Section III, Subsection K) of 42 CFR Part 82, making it part of the rule itself would formalize the change process, significantly strengthening assurance that review by the Advisory Board of proposed changes will occur.''

HHS Response: HHS accepts this recommendation by the Board. Accordingly, as discussed above in response to public comments on peer-review, HHS has moved provisions for peer-review involving the Board from the preamble of the notice of proposed rulemaking into the body of the rule itself. These provisions can be found at 42 CFR 82.30–82.33 (Subpart E).

Board Comment #2: ''The Advisory Board requests that the term 'validated', as used in Section 82.10(j), be either defined or clarified.''

HHS Response: HHS has clarified this section by eliminating any reference to validation, which has a specific meaning in scientific work which was not intended. The point of the text, which is now revised, was to indicate that NIOSH would determine that these data are assigned correctly and complete, before developing the exposure matrix discussed under the provision.

Board Comment #3: ''The Advisory Board recommends that NIOSH clarify 82.10(m), (n), and (o) in regards to the steps and timeline required for the claimants, or authorized representatives of the claimants, to provide information to NIOSH and to sign or submit form OCAS–1. NIOSH should ensure that the claimants, or authorized representatives of the claimants, have adequate time to obtain and submit additional information to NIOSH.''

HHS Response: HHS has revised §§ 82.10(l), (m), and (n) to clarify the procedure and time for the claimants or their authorized representatives to provide final information and sign and submit form OCAS–1, permitting NIOSH to complete the dose reconstruction. The new provisions clarify that NIOSH may allow claimants time to obtain and provide NIOSH with additional relevant information, after NIOSH has provided to the claimant OCAS–1, and before the 60 day deadline to submit OCAS–1 is applied. The public should also note that claimants will not receive OCAS–1 for signature before they have completed their initial interview session or sessions, received a summary of their initial interview for their review and revisions, and received for review a draft dose reconstruction report.

Board Comment #4: ''The Advisory Board recommends that § 82.18, concerning the use of ICRP models, be clarified so as to clearly indicate that NIOSH intends to use current ICRP models.''

HHS Response: HHS has clarified its intent to use current ICRP models in the text of this section, consistent with discussion of this provision in the preamble of the interim final rule and this final rule.

Board Comment #5: ''The Advisory Board recommends that the last sentence in § 82.28 (b), be clarified in regards to the coverage of the Privacy Act.''

HHS Response: The Board was concerned that the rule does not clearly indicate that certain researchers who follow specific procedures under the Privacy Act to protect confidential information may have access to names of claimants, covered employees, and other confidential information. HHS has clarified the text of this provision accordingly.

IV. Summary of the Rule

Congress, in enacting EEOICPA, created a new Energy Employees Occupational Illness Compensation Program to ensure an efficient, uniform, and adequate compensation system for certain employees. Under Executive Order 13179, the President assigned primary responsibility for administering the program to DOL. The President assigned various technical responsibilities for policymaking and assistance to HHS. Included among these is promulgation of this rule to establish methods NIOSH will apply to conduct dose reconstructions for covered employees seeking compensation for cancer, other than as members of the Special Exposure Cohort

seeking compensation for a specified cancer. NIOSH dose reconstructions will be used by DOL to estimate the probability that the cancers of these covered employees were related to radiation exposures at covered facilities.

Introduction

Sections 82.0 and 82.1 briefly describe how these regulations relate to DOL authorities under EEOICPA and the assignment of authority for these regulations to HHS. In § 82.2, HHS provides a general introduction to dose reconstruction and describes the hierarchy of information to be relied upon for dose reconstructions. This hierarchy gives preference to individual radiation monitoring data, if complete and adequate, and provides for use of information on the workplace environment and radiation exposures for interpretation and as a secondary source of data, and provides for use of reasonable and scientific assumptions in lieu of certain data when the workplace environment cannot be fully characterized. HHS believes this approach would give due weight to the potentially most precise data, but would take into account the limitations of such data and its availability.

Section 82.3 summarizes the specific provisions of EEOICPA directing HHS in the development of this regulation and NIOSH in the conduct of dose reconstructions under this regulation. Section 82.4 describes how DOL will use the results of NIOSH dose reconstructions for the adjudication of claims.

Definitions

Section 82.5 defines the principal terms used in this part. It includes terms specifically defined in EEOICPA that, for the convenience of the reader of this part, are repeated in this section. It clarifies the definition of radiation. Section 3621(16) of EEOICPA defines radiation as ionizing radiation in the form of alpha or beta particles, neutrons, gamma rays, or accelerated ions or subatomic particles from accelerator machines. The rule elaborates upon this definition, specifically including x rays, protons and other particles capable of producing ions in the body, which are components of ionizing radiation exposures experienced by nuclear weapons production workers. In addition, for clarity the definition in this rule explicitly excludes non-ionizing forms of radiation, such as radio-frequency radiation and microwaves.

The definition of EEOICPA has been revised to reflect the codification of the Act in the United States Code.

Dose Reconstruction Process

Section 82.10 provides an overview of the major elements of the dose reconstruction process that NIOSH will implement under EEOICPA. It describes the steps in the process, the sources and types of information that will be collected and analyzed, the role of the claimants in developing a factual basis for dose reconstruction, the types of analyses, and criteria that will direct NIOSH to ensure dose reconstructions produce reasonable dose estimates and serve claimants efficiently.

NIOSH will obtain available monitoring data and information on the workplace environment and practices from DOE and other sources. NIOSH will interview the claimant to obtain information and to report to the claimant on dose reconstruction results and the methods and data used to produce the results. NIOSH will take measures to produce results as efficiently as possible, so that adjudication of the claim by DOL can be resumed and completed in a timely fashion. These measures include limiting the dose reconstruction process to use less detailed or precise estimates for claims for which it is evident that further research and analysis will not affect the outcome of the claim.

For example, under these regulations, if it is evident from the record of external radiation dose alone that an employee incurred a sufficiently high level of dose to have the claim accepted by DOL for compensation (a dose that would result in a probability of causation of 50% or higher), NIOSH would conclude the process without continuing with time consuming research and analysis to estimate internal dose. Instead, NIOSH would immediately report the limited dose estimate, based on external dose only, to the claimant and DOL, along with an explanation of the reason for limiting the dose reconstruction process.

Similarly, if, for example, records and information establish that an employee incurred radiation doses evidently below a level that could result in compensation, NIOSH would substitute worst-case assumptions for additional research and analysis, to complete and report on the dose reconstruction without delay.

This approach will provide more timely compensation for claims for which it is evident the claimant will qualify for compensation, and more timely results and adjudication for claims for which it is evident further research and analysis will not produce a compensable level of radiation dose.

Section 82.10(j) has been revised, as indicated above in the discussion of public comments, to remove Table 1—Radiation Weighting Factors from the rule. Instead, this section simply indicates NIOSH will use current ICRP weighting factors. Inclusion of this table in the rule would require HHS to re-promulgate this section of the rule and the table as these weighting factors are updated by ICRP.

Sections 82.10(l), (m), and (n) have been revised, as indicated above in the discussion of recommendations by the Advisory Board on Radiation and Worker Health, to clarify the opportunity for the claimant to provide additional information to NIOSH after NIOSH has provided the claimant with a draft dose reconstruction report. The revisions also clarify the application of a 60 day deadline for the claimant to certify that they have completed providing information, such that NIOSH can conclude the dose reconstruction.

Section 82.11 defines the subset of claimants under EEOICPA for whom NIOSH will conduct dose reconstructions. NIOSH will attempt to conduct dose reconstructions for all claims forwarded to NIOSH from DOL. This includes all covered employees seeking compensation for cancer, other than as members of the Special Exposure Cohort seeking compensation for a specified cancer, as determined by DOL.

Section 82.12 describes NIOSH procedures for notifying any claimants for whom a dose reconstruction cannot be completed because of insufficient information to reasonably estimate the dose potentially incurred by the covered employee. NIOSH will notify the claimant and DOL that a dose reconstruction cannot be completed and describe the basis for this finding. In these cases, the claimant would have the opportunity to seek administrative review of this result after DOL produces a recommended decision to deny the claim, based on the report from NIOSH that there is insufficient evidence to complete a dose reconstruction. For a claim in which the employee has a specified cancer, the claimant might still be eligible for compensation under EEOICPA. Classes of covered employees have the option to petition HHS to be added to the Special Exposure Cohort. NIOSH will provide claimants for whom it cannot complete a dose reconstruction any information and forms provided by HHS for classes of employees to petition HHS. HHS is establishing procedures to consider such petitions, as required under Section 7384q of EEOICPA and Section 2(b) of E.O. 13179. Proposed

procedures will be published soon in the **Federal Register**.

Sections 82.13 and 82.14 describe in detail the sources and examples of the types of information NIOSH will use in dose reconstructions. DOE and claimants will be the primary sources of information. Information types include: subject and employment information, worker monitoring data, monitoring program data, workplace monitoring data, workplace characterization data, and process descriptions for each work location. The actual use of this wide range of information will be determined for each claim individually, based on the types of information available and necessary. HHS has revised these sections in response to public comments discussed above to ensure the types of information that might be used in dose reconstructions under this rule include any possibilities HHS has not specified.

Sections 82.15–82.17 describe how NIOSH will evaluate the completeness and adequacy of monitoring data and how NIOSH would remedy limitations, applying the general approach described in § 82.2 and making use of the data sources and types described in §§ 82.13 and 82.14. NIOSH will evaluate the completeness and adequacy of monitoring data by various means, such as evaluating associated information on the workplace environment and practices, evaluating the monitoring technology, and evaluating other sources of information. NIOSH will remedy data limitations using established dose reconstruction practices, such as interpolating from recorded doses to estimate unrecorded doses, and substituting monitoring data from comparably exposed workers.

Sections 82.18–82.19 describe how NIOSH will address salient technical issues of calculating internal dose and taking into account uncertainty with respect to dose information. Internal dose is the radiation dose received by radioactive materials taken into the body, such as by inhalation or ingestion. It is important because it accumulates year after year, increasing the risk of certain cancers over time. NIOSH will use current ICRP models for calculating internal dose and accompany dose estimates with uncertainty distributions. DOL will use these distributions with appropriate statistical methods to take into account uncertainty about the dose when calculating probability of causation for a claim.

As discussed in response to public comments above, HHS has added new language to § 82.18 to specify how NIOSH will select from among existing ICRP models to calculate internal dose for a cancer site that has not been addressed by ICRP.

Reporting and Review of Dose Reconstruction Results

Sections 82.25 and 82.26 describe in detail NIOSH procedures for reporting the results of dose reconstructions to claimants and DOL, specifying the timing, content, and form of the dose reconstruction reports.

Section 82.27 describes how and when claimants can obtain reviews of NIOSH dose reconstructions. NIOSH will review dose reconstructions upon request by DOL under DOL procedures for claimants seeking review of dose reconstructions. These procedures also allow for DOL to request reviews of dose reconstruction upon its own initiative; for example, to request review of previously completed dose reconstructions to reflect updated scientific methods.

As discussed above in response to public comments, HHS has revised this section to allow NIOSH to review completed dose reconstructions on its own initiative, in response to new information or scientific updates that could substantially increase the radiation doses NIOSH had estimated. HHS also revised this section to clarify that NIOSH will report to claimants, DOL, and DOE on NIOSH reviews of completed dose reconstructions conducted under this section.

Updating the Scientific Elements Underlying Dose Reconstructions

Section 82.30–82.33 describe the procedures NIOSH will follow to update the scientific elements underlying NIOSH dose reconstructions to maintain a dose reconstruction program that is reasonably current with progress in science. An example of such an update would be the incorporation of a newly published ICRP model for estimating internal dose. Updates may also be recommended by the public at any time.

The Advisory Board on Radiation and Worker Health will consider all proposals for updates in its public meetings, and the public will have an opportunity to comment on the proposals. To facilitate public participation, NIOSH will periodically publish a notice in the **Federal Register** informing the public of proposed updates, as well as notifying the public of proposed updates to be considered at upcoming meetings of the Advisory Board. NIOSH will also publish a notice in the **Federal Register** notifying the public of the completion of updates. In the notice, NIOSH will address relevant public comments and recommendations from the Advisory Board.

V. Significant Regulatory Action (Executive Order 12866)

This rule is being treated as a ''significant regulatory action'' within the meaning of Executive Order (E.O.) 12866 because it raises novel or legal policy issues arising out of the legal mandate established by EEOICPA. The rule is designed to establish practical methods, grounded in current science, to fairly and efficiently assist claimants and support DOL in the adjudication of applicable claims seeking compensation for cancer under EEOICPA. NIOSH will apply the methods to produce reasonable, scientifically supported estimates of the radiation doses incurred by covered employees subject to the claims, as permitted by available data and information. The financial cost to the federal government of producing these estimates is expected to be several thousand dollars per claim, on average.

The rule carefully explains the manner in which the regulatory action is consistent with the mandate for this action under section 3623(d) of EEOICPA and implements the detailed requirements concerning this action under this section of EEOICPA. The rule does not interfere with State, local, and tribal governments in the exercise of their governmental functions.

The rule is not considered economically significant, as defined in section 3(f)(1) of the Executive Order 12866. It has a subordinate role in the adjudication of claims under EEOICPA, serving as one element of an adjudication process administered by DOL under 20 CFR Parts 1 and 30. DOL has determined that its rule fulfills the requirements of Executive Order 12866 and provides estimates of the aggregate cost of benefits and administrative expenses of implementing EEOICPA under its rule (see FR 28948, May 25, 2001). OMB has reviewed this rule for consistency with the President's priorities and the principles set forth in E.O. 12866.

VI. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, requires each agency to consider the potential impact of its regulations on small entities including small businesses, small governmental units, and small not-for-profit organizations. We certify that this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA. This rule affects only DOL, DOE, HHS, and some individuals filing compensation claims under EEOICPA. Therefore, a regulatory

flexibility analysis as provided for under RFA is not required.

VII. What Are the Paperwork and Other Information Collection Requirements (Subject to the Paperwork Reduction Act) Imposed Under This Rule?

Under the Paperwork Reduction Act of 1995, a Federal agency shall not conduct or sponsor a collection of information from ten or more persons other than Federal employees unless the agency has submitted a Standard Form 83, Clearance Request, and Notice of Action, to the Director of the Office of Management and Budget (OMB), and the Director has approved the proposed collection of information. A person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The Paperwork Reduction Act is applicable to the data collection aspects of this rule.

NIOSH has obtained clearance from OMB to collect data under EEOICPA.

In performance of its dose reconstruction responsibilities under the Act, NIOSH will interview claimants individually and provide them with the opportunity, through a structured interview, to assist NIOSH in documenting the work history of the employee (characterizing the actual work tasks performed), identifying incidents that may have resulted in undocumented radiation exposures, characterizing radiation protection and monitoring practices, and identifying co-workers, radiation protection management and staff, line managers, and other witnesses, if NIOSH determines this is necessary, to confirm undocumented information. In this process, NIOSH will use a computer assisted telephone interview (CATI) system, which will allow interviews to be conducted more efficiently and quickly than would be the case with a paper-based interview instrument.

NIOSH will use the data collected in this process to complete an individual dose reconstruction that accounts for radiation dose, including unmonitored or inadequately monitored dose, incurred by the employee in the performance of duty for DOE nuclear weapons production programs. After dose reconstruction, NIOSH will provide a draft of the dose reconstruction report to the claimant and perform a brief follow-up interview with the claimant to explain the results and to allow the claimant to confirm or question the record NIOSH has compiled. This will also be the final opportunity for the claimant to supplement the dose reconstruction record.

At the conclusion of the dose reconstruction process, the claimant will be requested to submit to NIOSH a form (OCAS–1) to confirm that the claimant has completed providing information to NIOSH for the dose reconstruction. The form will notify the claimant that signing the form allows NIOSH to provide a final dose reconstruction report to DOL and closes the record on data to be used for the dose reconstruction. DOL will use data from the dose reconstruction report to determine the probability that the cancer(s) of the covered employee may have been caused by radiation doses incurred in the performance of duty at a DOE or AWE facility.

There will be no cost to respondents for this data collection.

VIII. Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), the Department will report to Congress promulgation of this rule prior to its effective date. The report will state that the Department has concluded that this rule is not a ''major rule'' because it is not likely to result in an annual effect on the economy of $100 million or more. However, this rule has a subordinate role in the adjudication of claims under EEOICPA, serving as one element of an adjudication process administered by DOL under 20 CFR parts 1 and 30. DOL has determined that its rule is a ''major rule'' because it will likely result in an annual effect on the economy of $100 million or more.

IX. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 *et seq.*) directs agencies to assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector, ''other than to the extent that such regulations incorporate requirements specifically set forth in law.'' For purposes of the Unfunded Mandates Reform Act, this rule does not include any Federal mandate that may result in increased annual expenditures in excess of $100 million by State, local or tribal governments in the aggregate, or by the private sector.

X. Executive Order 12988 (Civil Justice)

This rule has been drafted and reviewed in accordance with Executive Order 12988, Civil Justice Reform and will not unduly burden the Federal court system. Dose reconstruction may be an element in reviews of DOL adverse decisions in the United States District Courts pursuant to the Administrative Procedure Act. However, DOL has attempted to minimize that burden by providing claimants an opportunity to seek administrative review of adverse decisions, including those involving dose reconstruction. This rule provides a clear legal standard for HHS and DOL to apply regarding dose reconstruction. This rule has been reviewed carefully to eliminate drafting errors and ambiguities.

XI. Executive Order 13132 (Federalism)

The Department has reviewed this rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have ''federalism implications.'' The rule does not ''have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

XII. Executive Order 13045 (Protection of Children From Environmental, Health Risks and Safety Risks)

In accordance with Executive Order 13045, HHS has evaluated the environmental health and safety effects of this rule on children. The agency has determined that the rule will not affect children.

XIII. Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use)

In accordance with Executive Order 13211, HHS has evaluated the effects of this rule on energy supply, distribution or use, and has determined that this rule is not likely to have a significant adverse effect on them.

XIV. Effective Date and Information Collection Approval

The Secretary has determined, pursuant to 5 U.S.C. 553(d)(3), that there is good cause for this rule to be effective immediately to avoid undue hardship on and facilitate payment to eligible claimants.

The Office of Management and Budget (OMB) approved these information collection requirements on October 30, 2001, and assigned control number 0920–0530.

List of Subjects in 42 CFR Part 82

Cancer, Dose reconstruction, Government employees, Occupational safety and health, Nuclear materials,

Radiation protection, Radioactive materials, Workers' compensation.

Text of the Rule

For the reasons discussed in the preamble, the Department of Health and Human Services revises 42 CFR part 82 to read as follows:

PART 82—METHODS FOR CONDUCTING DOSE RECONSTRUCTION UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000

Subpart A—Introduction

Subpart B—Definitions

Subpart C—Dose Reconstruction Process

Subpart D—Reporting and Review of Dose Reconstruction Results

Subpart E—Updating Scientific Elements Underlying Dose Reconstructions

Authority: 42 U.S.C. 7384n(d) and (e); E.O. 13179, 65 FR 77487, 3 CFR, 2000 Comp., p. 321.

Subpart A—Introduction

§ 82.0 Background information on this part.

The Energy Employees Occupational Illness Compensation Program Act (EEOICPA), 42 U.S.C. 7384–7385 [1994, supp. 2001], provides for the payment of compensation benefits to covered employees and, where applicable, survivors of such employees, of the United States Department of Energy (''DOE''), its predecessor agencies and certain of its contractors and subcontractors. Among the types of illnesses for which compensation may be provided are cancers. There are two categories of covered employees with cancer under EEOICPA for whom compensation may be provided. The regulations that follow under this part apply only to the category of employees described under paragraph (a) of this section.

(a) One category is employees with cancer for whom a dose reconstruction must be conducted, as required under 20 CFR 30.115.

(b) The second category is members of the Special Exposure Cohort seeking compensation for a specified cancer, as defined under EEOICPA. The U.S. Department of Labor (DOL) which has primary authority for implementing EEOICPA, has promulgated regulations at 20 CFR 30.210 and 30.213 that identify current members of the Special Exposure Cohort and requirements for compensation. Pursuant to section 3626 of EEOICPA, the Secretary of HHS is authorized to add additional classes of employees to the Special Exposure Cohort.

§ 82.1 What is the purpose of this part?

The purpose of this part is to provide methods for determining a reasonable estimate of the radiation dose received by a covered employee with cancer under EEOICPA, through the completion of a dose reconstruction. These methods will be applied by the National Institute for Occupational Safety and Health (NIOSH) in a dose reconstruction program serving claimants under EEOICPA, as identified under § 82.0.

§ 82.2 What are the basics of dose reconstruction?

The basic principle of dose reconstruction is to characterize the radiation environments to which workers were exposed and to then place each worker in time and space within this exposure environment. Then methods are applied to translate exposure to radiation into quantified radiation doses at the specific organs or tissues relevant to the types of cancer occurring among the workers. A hierarchy of methods is used in a dose reconstruction, depending on the nature of the exposure conditions and the type, quality, and completeness of data available to characterize the environment.

(a) If found to be complete and adequate, individual worker monitoring data, such as dosimeter readings and bioassay sample results, are given the highest priority in assessing exposure. These monitoring data are interpreted using additional data characterizing the workplace radiation exposures. If radiation exposures in the workplace environment cannot be fully characterized based on available data, default values based on reasonable and scientific assumptions may be used as substitutes. For dose reconstructions conducted in occupational illness compensation programs, this practice may include use of assumptions that represent the worst case conditions. For example, if the solubility classification of an inhaled material can not be determined, the dose reconstruction would use the classification that results in the largest dose to the organ or tissue relevant to the cancer and that is possible given existing knowledge of the material and process.

(b) If individual monitoring data are not available or adequate, dose reconstructions may use monitoring results for groups of workers with comparable activities and relationships to the radiation environment. Alternatively, workplace area monitoring data may be used to estimate the dose. As with individual worker monitoring data, workplace exposure characteristics are used in combination with workplace monitoring data to estimate dose.

(c) If neither adequate worker nor workplace monitoring data are available, the dose reconstruction may rely substantially on process description information to analytically develop an exposure model. For internal exposures,

this model includes such factors as the quantity and composition of the radioactive substance (the source term), the chemical form, particle size distribution, the level of containment, and the likelihood of dispersion.

§ 82.3 What Are the Requirements for Dose Reconstruction Under EEOICPA?

(a) Dose reconstructions are to be conducted for the following covered employees with cancer seeking compensation under EEOICPA: An employee who was not monitored for exposure to radiation at DOE or Atomic Weapons Employer (AWE) facilities; an employee who was monitored inadequately for exposure to radiation at such facilities; or an employee whose records of exposure to radiation at such facility are missing or incomplete. Technical limitations of radiation monitoring technology and procedures will require HHS to evaluate each employee's recorded dose. In most, if not all cases, monitoring limitations will result in possibly undetected or unrecorded doses, which are estimated using commonly practiced dose reconstruction methods and would have to be added to the dose record.

(b) Section 7384(n)(e) of EEOICPA requires the reporting of radiation dose information resulting from dose reconstructions to the covered employees for whom claims are being adjudicated. DOE is specifically charged with this responsibility but the Department of Health and Human Services (HHS), which will be producing the dose reconstruction information, will report its findings directly to the claimant, as well as to DOL and DOE. HHS will also make available to researchers and the general public information on the assumptions, methodology, and data used in estimating radiation doses, as required by EEOICPA.

§ 82.4 How Will DOL Use the Results of the NIOSH Dose Reconstructions?

Under 42 CFR part 81, DOL will apply dose reconstruction results together with information on cancer diagnosis and other personal information provided to DOL by the claimant to calculate an estimated probability of causation. This estimate is the probability that the cancer of the covered employee was caused by radiation exposure at a covered facility of DOE or an Atomic Weapons Employer (AWE).

Subpart B—Definitions

§ 82.5 Definition of terms used in this part.

(a) *Atomic weapons employer* (AWE) means any entity, other than the United States, that:

(1) processed or produced, for use by the United States, material that emitted radiation and was used in the production of an atomic weapon, excluding uranium mining and milling; and,

(2) is designated by the Secretary of Energy as an atomic weapons employer for purposes of EEOICPA.

(b) *Bioassay* means the determination of the kinds, quantities, or concentrations, and in some cases, locations of radioactive material in the human body, whether by direct measurement or by analysis, and evaluation of radioactive material excreted or eliminated by the body.

(c) *Claimant* means the individual who has filed with the Department of Labor for compensation under EEOICPA.

(d) *Covered employee* means, for the purposes of this part, an individual who is or was an employee of DOE, a DOE contractor or subcontractor, or an atomic weapons employer, and for whom DOL has requested HHS to perform a dose reconstruction.

(e) *Covered facility* means any building, structure, or premises, including the grounds upon which such building, structure, or premise is located:

(1) In which operations are, or have been, conducted by, or on behalf of, the DOE (except for buildings, structures, premises, grounds, or operations covered by Executive Order 12344, dated February 1, 1982, pertaining to the Naval Nuclear Propulsion Program); and,

(2) With regard to which the DOE has or had:

(i) A proprietary interest; or,

(ii) Entered into a contract with an entity to provide management and operation, management and integration, environmental remediation services, construction, or maintenance services; or

(3) A facility owned by an entity designated by the Secretary of Energy as an atomic weapons employer for purposes of EEOICPA that is or was used to process or produce, for use by the United States, material that emitted radiation and was used in the production of an atomic weapon, excluding uranium mining or milling.

(f) *DOE* means the U.S. Department of Energy, and includes predecessor agencies of DOE, including the Manhattan Engineering District.

(g) *DOL* means the U.S. Department of Labor.

(h) *EEOICPA* means the Energy Employees Occupational Illness Compensation Program Act of 2000, 42 U.S.C. 7384–7385 [1994, supp. 2001].

(i) *Equivalent dose* is the absorbed dose in a tissue multiplied by a radiation weighting factor to account for differences in the effectiveness of the radiation in inducing cancer.

(j) *External dose* means that portion of the equivalent dose that is received from radiation sources outside of the body.

(k) *Internal dose* means that portion of the equivalent dose that is received from radioactive materials taken into the body.

(l) *NIOSH* means the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

(m) *Primary cancer* means a cancer defined by the original body site at which the cancer was incurred, prior to any spread (metastasis) resulting in tumors at other sites in the body.

(n) *Probability of causation* means the probability or likelihood that a cancer was caused by radiation exposure incurred by a covered employee in the performance of duty. In statistical terms, it is the cancer risk attributable to radiation exposure divided by the sum of the baseline cancer risk (the risk to the general population) plus the cancer risk attributable to the radiation exposure. This concept is further explained under 42 CFR part 81, which provides guidelines by which DOL will determine probability of causation under EEOICPA.

(o) *Radiation* means ionizing radiation, including alpha particles, beta particles, gamma rays, x rays, neutrons, protons and other particles capable of producing ions in the body. For purposes of this rule, radiation does not include sources of non-ionizing radiation such as radio-frequency radiation, microwaves, visible light, and infrared or ultraviolet light radiation.

(p) *Specified cancer* is a term defined in Section 3621(17) of EEOICPA and 20 CFR 30.5(dd) that specifies types of cancer that, pursuant to 20 CFR part 30, may qualify a member of the Special Exposure Cohort for compensation. It includes leukemia (other than chronic lymphocytic leukemia), multiple myeloma, non-Hodgkin's lymphoma, and cancers of the lung (other than carcinoma in situ diagnosed at autopsy), thyroid, male breast, female breast, esophagus, stomach, pharynx, small intestine, pancreas, bile ducts, gall bladder, salivary gland, urinary bladder, brain, colon, ovary, liver (not associated

with cirrhosis or hepatitis), and bone. Pursuant to section 2403 of Public Law 107–20, this definition will include renal cancer effective October 1, 2001.

(q) *Uncertainty distribution* is a statistical term meaning a range of discrete or continuous values arrayed around a central estimate, where each value is assigned a probability of being correct.

(r) *Worst-case assumption* is a term used to describe a type of assumption used in certain instances for certain dose reconstructions conducted under this rule. It assigns the highest reasonably possible value, based on reliable science, documented experience, and relevant data, to a radiation dose of a covered employee.

Subpart C—Dose Reconstruction Process

§ 82.10 Overview of the dose reconstruction process.

(a) Upon receipt of a claims package from the Department of Labor, as provided under 20 CFR part 30, NIOSH will request from DOE records on radiation dose monitoring and radiation exposures associated with the employment history of the covered employee. Additionally, NIOSH may compile data, and information from NIOSH records that may contribute to the dose reconstruction. For each dose reconstruction, NIOSH will include records relevant to internal and external exposures to ionizing radiation, including exposures from medical screening x rays that were required as a condition of employment.

(b) NIOSH will evaluate the initial radiation exposure record compiled to: Reconcile the exposure record with the reported employment history, as necessary; complete preliminary calculations of dose, based upon this initial record, and prepare to consult with the claimant. Any discrepancies in the employment history information will be reconciled with the assistance of DOE, as necessary.

(c) NIOSH will interview the claimant. The interview may be conducted in one or more sessions. The purpose of the interview is to:

(1) Explain the dose reconstruction process;

(2) Confirm elements of the employment history transmitted to NIOSH by DOL;

(3) Identify any relevant information on employment history that may have been omitted;

(4) Confirm or supplement monitoring information included in the initial radiation exposure record;

(5) Develop detailed information on work tasks, production processes, radiologic protection and monitoring practices, and incidents that may have resulted in undocumented radiation exposures, as necessary;

(6) Identify co-workers and other witnesses with information relevant to the radiation exposures of the covered worker to supplement or confirm information on work experiences, as necessary.

(d) NIOSH will provide a report to the claimant summarizing the findings of the interview, titled: ''NIOSH Claimant Interview under EEOICPA.'' The report will also notify the claimant of the opportunity to contact NIOSH if necessary, by a specified date, to make any written corrections or additions to information provided by the claimant during the interview process.

(e) Information provided by the claimant will be accepted and used for dose reconstruction, providing it is reasonable, supported by substantial evidence, and is not refuted by other evidence. In assessing whether the information provided by the claimant is supported by substantial evidence, NIOSH will consider:

(1) Consistency of the information with other information in the possession of NIOSH, from radiation safety programs, research, medical screening programs, labor union documents, worksite investigations, dose reconstructions conducted by NIOSH under EEOICPA, or other reports relating to the circumstances at issue;

(2) Consistency of the information with medical records provided by the claimant;

(3) Consistency of the information with practices or exposures demonstrated by the dose reconstruction record developed for the claimant; and,

(4) Confirmation of information by co-workers or other witnesses.

(f) NIOSH will seek to confirm information provided by the claimant through review of available records and records requested from DOE.

(g) As necessary, NIOSH will request additional records from DOE to characterize processes and tasks potentially involving radiation exposure for which dose and exposure monitoring data is incomplete or insufficient for dose reconstruction.

(h) NIOSH will review the adequacy of monitoring data and completeness of records provided by DOE. NIOSH will request certification from DOE that record searches requested by NIOSH have been completed.

(i) As necessary, NIOSH will characterize the internal and external exposure environments for parameters known to influence the dose. For internal exposures, examples of these parameters include the mode of intake, the composition of the source term (i.e., the radionuclide type and quantity), the particle size distribution and the absorption type. When it is not possible to characterize these parameters, NIOSH may use default values, when they can be established reasonably, fairly, and based on relevant science. For external exposures, the radiation type (gamma, x-ray, neutron, beta, or other charged particle) and radiation energy spectrum will be evaluated. When possible, the effect of non-uniformity and geometry of the radiation exposure will be assessed.

(j) For individual monitoring records that are incomplete, NIOSH may assign doses using techniques discussed in § 82.16. Once the resulting data set is complete, NIOSH will construct an occupational exposure matrix, using the general hierarchical approach discussed in § 82.2. This matrix will contain the estimated annual equivalent dose(s) to the relevant organ(s) or tissue(s), for the period from the initial date of potential exposure at a covered facility until the date the cancer was diagnosed. The equivalent dose(s) will be calculated using the current, standard radiation weighting factors from the International Commission on Radiological Protection. [1]

(k) At any point during steps of dose reconstruction described in paragraphs (f) through (j) of this section, NIOSH may determine that sufficient research and analysis has been conducted to complete the dose reconstruction. Research and analysis will be determined sufficient if one of the following three conditions is met:

(1) From acquired experience, it is evident the estimated cumulative dose is sufficient to qualify the claimant for compensation (*i.e.,* the dose produces a probability of causation of 50% or greater);

(2) Dose is determined using worst-case assumptions related to radiation exposure and intake, to substitute for further research and analyses; or,

(3) Research and analysis indicated under steps described in paragraphs (f)–(j) of this section have been completed. Worst-case assumptions will be employed under condition 2 to limit further research and analysis only for claims for which it is evident that further research and analysis will not produce a compensable level of radiation dose (a dose producing a probability of causation of 50% or

[1] The current weighting factors of the International Commission on Radiological Protection are provided in ICRP 60: ''1990 Recommendations of the International Commission on Radiological Protection.'' Ann. ICRP 21 (1–3):6.

greater), because using worst-case assumptions it can be determined that the employee could not have incurred a compensable level of radiation dose. For all claims in which worst-case assumptions are employed under condition 2, the reasoning that resulted in the determination to limit further research and analysis will be clearly described in the draft of the dose reconstruction results reported to the claimant under § 82.25 and in the dose reconstruction results reported to the claimant under § 82.26.

(l) After providing the claimant with a copy of a draft of the dose reconstruction report to be provided to DOL, NIOSH will conduct a closing interview with the claimant to review the dose reconstruction results and the basis upon which the results were calculated. This will be the final opportunity during the dose reconstruction process for the claimant to provide additional relevant information that may affect the dose reconstruction. The closing interview may require multiple sessions, if the claimant requires time to obtain and provide additional information, and to allow NIOSH time to integrate the new information into a new draft of the dose reconstruction report. NIOSH will determine whether to grant requests for time to provide additional information, based on whether the requests are reasonable and the claimant is actively seeking the information specified.

(m) Subject to any additional information provided by the claimant and revision of the draft dose reconstruction report under § 82.10(l), the claimant is required to return form OCAS–1 to NIOSH, certifying that the claimant has completed providing information and that the record for dose reconstruction should be closed. Upon receipt of the form, NIOSH will forward a final dose reconstruction report to DOL, DOE, and to the claimant.

(n) NIOSH will not forward the dose reconstruction report to DOL for adjudication without receipt of form OCAS–1 signed by the claimant or a representative of the claimant authorized pursuant to 20 CFR 30.600. If the claimant or the authorized representative of the claimant fails to sign and return form OCAS–1 within 60 days, or 60 days following the claimant's final provision of additional information and receipt of a revised draft dose reconstruction report under § 82.10 (l), whichever occurs last, after notifying the claimant or the authorized representative, NIOSH may administratively close the dose reconstruction and notify DOL of this action. Upon receiving this notification by NIOSH, DOL may administratively close the claim.

(o) Once actions under § 82.10 (m) are completed, the record for dose reconstruction shall be closed unless reopened at the request of DOL under 20 CFR part 30.

§ 82.11 For which claims under EEOICPA will NIOSH conduct a dose reconstruction?

NIOSH will conduct a dose reconstruction for each claim determined by DOL to be a claim for a covered employee with cancer under DOL regulations at 20 CFR 30.210(b), subject to the limitation and exception noted in § 82.12. Claims for covered employees who are members of the Special Exposure Cohort seeking compensation for a specified cancer, as determined by DOL under 20 CFR 30.210(a), do not require and will not receive a dose reconstruction under this rule.

§ 82.12 Will it be possible to conduct dose reconstructions for all claims?

It is uncertain whether adequate information of the types outlined under § 82.14 will be available to complete a dose reconstruction for every claim eligible under § 82.11.

(a) NIOSH will notify in writing any claimants for whom a dose reconstruction cannot be completed once that determination is made, as well as in the closing interview provided for under § 82.10(l).

(b) Notification will describe the basis for finding a dose reconstruction cannot be completed, including the following:

(1) A summary of the information obtained from DOE and other sources; and, (2) a summary of necessary information found to be unavailable from DOE and other sources.

(c) NIOSH will notify DOL and DOE when it is unable to complete a dose reconstruction for the claimant. This will result in DOL producing a recommended decision to deny the claim, since DOL cannot determine probability of causation without a dose estimate produced by NIOSH under this rule.

(d) A claimant for whom a dose reconstruction cannot be completed, as indicated under this section, may have recourse to seek compensation under provisions of the Special Exposure Cohort (see 20 CFR part 30). Pursuant to section 7384q of EEOICPA, the Secretary of HHS is authorized to add classes of employees to the Special Exposure Cohort. NIOSH will provide the claimant with any information and forms that HHS provides to classes of employees seeking to petition to be added to the Special Exposure Cohort.

§ 82.13 What sources of information may be used for dose reconstructions?

NIOSH will use the following sources of information for dose reconstructions, as necessary:

(a) DOE and its contractors, including Atomic Weapons Employers and the former worker medical screening program;

(b) NIOSH and other records from health research on DOE worker populations;

(c) Interviews and records provided by claimants;

(d) Co-workers of covered employees, or others with information relevant to the covered employee's exposure, that the claimant identified during the initial interview with NIOSH;

(e) Labor union records from unions representing employees at covered facilities of DOE or AWEs; and,

(f) Any other relevant information.

§ 82.14 What types of information could be used in dose reconstructions?

NIOSH will obtain the types of information described in this section for dose reconstructions, as necessary and available:

(a) *Subject and employment information*, including:

(1) Gender;

(2) Date of birth; and,

(3) DOE and/or AWE employment history, including: job title held by year, and work location(s): including site names(s), building numbers(s), technical area(s), and duration of relevant employment or tasks.

(b) *Worker monitoring data*, including:

(1) External dosimetry data, including external dosimeter readings (film badge, TLD, neutron dosimeters); and,

(2) Pocket ionization chamber data.

(c) *Internal dosimetry data*, including:

(1) Urinalysis results;

(2) Fecal sample results;

(3) In Vivo measurement results;

(4) Incident investigation reports;

(5) Breath radon and/or thoron results;

(6) Nasal smear results;

(7) External contamination measurements; and

(8) Other measurement results applicable to internal dosimetry.

(d) *Monitoring program data*, including:

(1) Analytical methods used for bioassay analyses;

(2) Performance characteristics of dosimeters for different radiation types;

(3) Historical detection limits for bioassay samples and dosimeter badges;

(4) Bioassay sample and dosimeter collection/exchange frequencies;

(5) Documentation of record keeping practices used to record data and/or administratively assign dose; and,

(6) Other information to characterize the monitoring program procedures and evaluate monitoring results.

(e) *Workplace monitoring data*, including:

(1) Surface contamination surveys;

(2) General area air sampling results;

(3) Breathing zone air sampling results;

(4) Radon and/or thoron monitoring results;

(5) Area radiation survey measurements (beta, gamma and neutron); and,

(6) Fixed location dosimeter results (beta, gamma and neutron); and,

(7) Other workplace monitoring results.

(f) *Workplace characterization data*, including:

(1) Information on the external exposure environment, including: radiation type (gamma, x-ray, proton, neutron, beta, other charged particle); radiation energy spectrum; uniformity of exposure (whole body vs partial body exposure); irradiation geometry;

(2) Information on work-required medical screening x rays; and,

(3) Other information useful for characterizing workplace radiation exposures.

(g) *Information characterizing internal exposures*, including:

(1) Radionuclide(s) and associated chemical forms;

(2) Results of particle size distribution studies;

(3) Respiratory protection practices; and

(4) Other information useful for characterizing internal exposures.

(h) *Process descriptions for each work location*, including:

(1) General description of the process;

(2) Characterization of the source term (i.e., the radionuclide and its quantity);

(3) Extent of encapsulation;

(4) Methods of containment;

(5) Other information to assess potential for irradiation by source or airborne dispersion radioactive material.

§ 82.15 How will NIOSH evaluate the completeness and adequacy of individual monitoring data?

(a) NIOSH will evaluate the completeness and adequacy of an individual's monitoring data provided by DOE through one or more possible measures including, but not limited to:

(1) Comparisons with information provided by claimants, co-workers, and other witnesses;

(2) Comparisons with available information on area monitoring, production processes, and radiologic protection programs;

(3) Comparisons with information documented in the records of unions representing covered employees;

(4) Comparisons with data available on co-workers; and

(5) Reviews of DOE contractor record systems.

(b) NIOSH will evaluate the instruments and procedures used to collect individual monitoring data to determine whether they adequately characterized the radiation environments in which the covered employee worked, (adequately for the purpose of dose reconstruction,) based on present-day scientific understanding. For external dosimeter measurements, this includes an evaluation of the dosimeter response to the radiation types (gamma, x-ray, neutron, beta, or other charged particle) and the associated energy spectrum. For internal exposure, the methods used to analyze bioassay samples will be reviewed to determine their ability to detect the radionuclides present in the work environment. An analysis of the monitoring or exchange frequencies for the monitoring programs will also be conducted to determine the potential for undetected dose.

§ 82.16 How will NIOSH add to monitoring data to remedy limitations of individual monitoring and missed dose?

(a) For external dosimeter results that are incomplete due to historical record keeping practices, NIOSH will use commonly practiced techniques, such as those described in the NIOSH Research Issues Workshop,[2] to estimate the missing component of dose and to add this to the total dose estimate. For monitoring periods where external dosimetry data are missing from the records, NIOSH will estimate a claimant's dose based on interpolation, using available monitoring results from other time periods close to the period in question, or based on monitoring data on other workers engaged in similar tasks.

(b) NIOSH will review historical bioassay sample detection limits and monitoring frequencies to determine, when possible, the minimum detectable dose for routine internal dose monitoring programs. This ''missed dose'' will establish the upper limit of internal dose that a worker could have received for periods when bioassay sample analysis results were below the detection limit. Using ICRP biokinetic models, NIOSH will estimate the internal dose and include an associated uncertainty distribution.

§ 82.17 What types of information could be used to supplement or substitute for individual monitoring data?

Three types of information could be used:

(a) Monitoring data from co-workers, if NIOSH determines they had a common relationship to the radiation environment; or,

(b) A quantitative characterization of the radiation environment in which the covered employee worked, based on an analysis of historical workplace monitoring information such as area dosimeter readings, general area radiation and radioactive contamination survey results, air sampling data; or,

(c) A quantitative characterization of the radiation environment in which the employee worked, based on analysis of data describing processes involving radioactive materials, the source materials, occupational tasks and locations, and radiation safety practices.

§ 82.18 How will NIOSH calculate internal dose to the primary cancer site(s)?

(a) The calculation of dose from ingested, inhaled or absorbed radioactivity involves the determination of the types and quantities of radionuclides that entered the body. NIOSH will use the results of all available bioassay monitoring information as appropriate, based on assessment of the technical characteristics of the monitoring program. If bioassay monitoring data are unavailable or inadequate, the dose reconstruction will rely on the results of air sampling measurements, radiation sources, work processes and practices, and incidents involving radiation contamination, as necessary.

(b) NIOSH will calculate the dose to the organ or tissue of concern using the appropriate current metabolic models published by ICRP. Using data available to NIOSH, the models will be based on exposure conditions representative of the work environment. When NIOSH cannot establish exposure conditions with sufficient specificity, the dose calculation will assume exposure conditions that maximize the dose to the organ under consideration. When the cancer covered by a claim is in a tissue not covered by existing ICRP models, NIOSH will use the ICRP model that best approximates the model needed, while giving the benefit of the doubt to the claimant. For internal exposures, NIOSH will select the highest dose estimate from among the modeled organs or tissues that do not concentrate the radionuclide.

[2] NIOSH [1995]. NIOSH research issues workshop: epidemiologic use of nondetectable values in radiation exposure measurements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 224647 (NTIS—PB 95189601).

(c) Internal doses will be calculated for each year of exposure from the date of initial exposure to the date of cancer diagnosis.

§ 82.19 How will NIOSH address uncertainty about dose levels?

The estimate of each annual dose will be characterized with a probability distribution that accounts for the uncertainty of the estimate. This information will be used by DOL in the calculation of probability of causation, under HHS guidelines for calculating probability of causation estimates at 42 CFR 81. In this way, claimants will receive the benefit of the doubt in cases in which the actual dose may have exceeded the best estimate calculated by NIOSH.

Subpart D—Reporting and Review of Dose Reconstruction Results

§ 82.25 When will NIOSH report dose reconstruction results, and to whom?

NIOSH will report dose reconstruction results to DOL and to the claimant, as provided for under § 82.10. Draft results will be reported to the claimant upon tentative completion of the dose reconstruction. Final results will be reported to the claimant, DOL and DOE after NIOSH receives certification from the claimant that the claimant has completed providing information to NIOSH for the dose reconstruction (Form OCAS–1).

§ 82.26 How will NIOSH report dose reconstruction results?

(a) NIOSH will provide dose reconstruction results to the claimant, DOL, and DOE in a report: ''NIOSH Report of Dose Reconstruction under EEOICPA.'' The report itself will not provide information on probability of causation, which DOL must calculate to determine a recommended decision on the claim.

(b) The report will include the following information, as relevant:

(1) Annual dose estimates (or a fraction thereof) related to covered employment for each year from the date of initial radiation exposure at a covered facility to the date of cancer diagnosis;

(2) Separate dose estimates for acute and chronic exposures, different types of ionizing radiation, and internal and external doses, providing internal dose information only for the organ or tissue relevant to the primary cancer site(s) established in the claim;

(3) Uncertainty distributions associated with each dose estimated, as necessary;

(4) Explanation of each type of dose estimate included in terms of its relevance for estimating probability of causation;

(5) Identification of any information provided by the claimant relevant to dose estimation that NIOSH decided to omit from the basis for dose reconstruction, justification for the decision, and if possible, a quantitative estimate of the effect of the omission on the dose reconstruction results; and

(6) A summary and explanation of information and methods applied to produce the dose reconstruction estimates, including any factual findings and the evidence upon which those findings are based.

(c) As provided under § 82.10(l), NIOSH staff will conduct a closing interview with claimants to explain the dose reconstruction report.

§ 82.27 How can claimants obtain reviews of their NIOSH dose reconstruction results by NIOSH?

(a) Claimants can seek reviews of their dose reconstruction through the processes established by DOL under 20 CFR 30. DOL will request NIOSH to review dose reconstructions under the following conditions, as provided under 20 CFR 30.318:

(1) DOL may determine that factual findings of the dose reconstruction do not appear to be supported by substantial evidence; or,

(2) Although the methodology established by HHS under this Part is binding on DOL, DOL may determine that arguments concerning the *application* of this methodology should be considered by NIOSH.

(b) NIOSH may review completed dose reconstructions on its own initiative and with the assistance of DOL to identify denied claims when either of the following circumstances arise:

(1) NIOSH obtains records or information on radiation exposures of DOE or AWE employees that could substantially increase the level of radiation doses estimated in the completed dose reconstructions; or

(2) NIOSH changes a scientific element underlying dose reconstructions according to the provisions of Subpart E of this rule and the change could substantially increase the level of radiation doses estimated in the completed dose reconstructions.

(c) When NIOSH completes the review of a dose reconstruction, NIOSH will provide a report describing the basis for the review, the methods employed in the review, and the review findings to the claimant, DOL, and DOE.

§ 82.28 Who can review NIOSH dose reconstruction files on individual claimants?

(a) Claimants and DOL will be provided individual dose reconstruction files, upon request. Claimants should note, however, that a complete summary of the data and methods used in a dose reconstruction will be included in the ''NIOSH Report of Dose Reconstruction under EEOICPA''.

(b) Researchers and the public will be provided limited access to NIOSH dose reconstruction files, subject to provisions and restrictions of the Privacy Act for the protection of confidential information on individuals.

Subpart E—Updating the Scientific Elements Underlying Dose Reconstructions

§ 82.30 How will NIOSH inform the public of any plans to change scientific elements underlying the dose reconstruction process to maintain methods reasonably current with scientific progress?

Periodically, NIOSH will publish a notice in the **Federal Register** notifying the public of plans to change scientific elements underlying the dose reconstruction process under EEOICPA to reflect scientific progress. Notice will include a summary of the planned changes and the expected completion date for such changes.

§ 82.31 How can the public recommend changes to scientific elements underlying the dose reconstruction process?

(a) At any time, the public can submit written recommendations to NIOSH for changes to scientific elements underlying the dose reconstruction process, based on relevant new research findings and technological advances. NIOSH will provide these recommendations to the Advisory Board on Radiation and Worker Health to be addressed at a public meeting of the Advisory Board, with notification provided to the source of the recommendations. Recommendations should be addressed to: Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS–R45, Cincinnati, Ohio 45226.

(b) The public can also submit recommendations by e-mail. Instructions will be provided on the NIOSH Internet homepage at www.cdc.gov/niosh/ocas.

§ 82.32 How will NIOSH make changes in scientific elements underlying the dose reconstruction process, based on scientific progress?

NIOSH will present proposed changes to the Advisory Board on Radiation and

Worker Health prior to implementation. These proposed changes will be summarized in a notice published in the **Federal Register**. The public will have the opportunity to comment on proposed changes at the meeting of the Advisory Board and/or in written comments submitted for this purpose. NIOSH will fully consider the comments of the Advisory Board and of the public before deciding upon any changes.

§ 82.33 How will NIOSH inform the public of changes to the scientific elements underlying the dose reconstruction process?

(a) NIOSH will publish a notice in the **Federal Register** informing the public of changes and the rationale for the changes. This notice will also provide a summary of the recommendations and comments received from the Advisory Board and the public, as well as responses to the comments.

(b) NIOSH may take into account other factors and employ other procedures than those specified in this subpart, if circumstances arise that require NIOSH to implement a change more immediately than the procedures in this subpart allow.

Dated: April 10, 2002.

Tommy G. Thompson,

Secretary, Department of Health and Human Services.

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